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Spermicides—Simplicity and Safety Are Major Assets

Summary. A decade ago, when hopes were high for new and better contraceptives, there seemed little room in expanding public and private family planning programs for such a simple and old-fashioned method as vaginal spermicides. Even now other methods offer advantages which jellies, creams, foams, foaming tablets, and suppositories seem to lack. Oral contraceptives, for example, provide convenient, nearly 100 percent effective protection for young, fertile women; IUDs are appropriate and almost equally effective for women who have had children; and sterilization is both effective and relatively free of side effects for couples who want no more children.

Is there any role for vaginal chemical spermicides? Are they effective? Do they make a useful contribution to voluntary family planning programs?

The answer is yes. If used properly, spermicides can be more than 95 percent effective. Even if they are not used properly all the time, spermicides are about 85 percent effective and meet important needs that other methods may not. They are:

- **safe**, with no proven systemic side effects or even any serious local reactions
- readily **available** from commercial sources without the need for a medical consultation or prescription
- **useful** as a simple, easily understood introduction to fertility control
- **convenient** for use by couples who have intercourse infrequently
- **appropriate** for short-term use or for adjunct use with other methods
- **acceptable** to women who might not otherwise use family planning and
- probably to some degree **protective** against venereal disease and certain other sexually related infections.

Spermicidal products available today come in five different forms: creams, jellies, foams in pressurized containers, foaming tablets, and suppositories. Each consists of (1) a relatively inert base material which physically blocks the passage of sperm and simultaneously serves as a carrier for (2) a chemically active ingredient, or spermicide, which incapacitates the sperm before it can reach the ovum. Base materials vary considerably, but most modern products rely on a single spermicide, commonly known as nonoxynol-9, to immobilize the sperm. A notable exception is the Japanese product Neo Sampoon foaming tablets, which contains TS-88, or menfegol. The safety of nonoxynol-9 and TS-88 are well-established, and an advisory panel of the US Food and Drug Administration has recommended classifying them safe and effective.

Availability

The availability of spermicidal methods is a major asset for any potential user in areas where doctors and clinics are scarce. Spermicides can be widely sold not only by chemists, or pharmacists, but also by vendors in small shops and bazaars. Moreover, they can often be advertised and promoted without rousing the opposition that has greeted attempts to advertise condoms or oral contraceptives to the public. As a result, community-based and social marketing programs either have added or plan to add spermicides to their product lines in 17 countries —Bangladesh, Brazil, Colombia, the Dominican Republic, Ecuador, Egypt, Grenada, Guatemala, Haiti, Mexico, Morocco, Panama, St. Vincent, South Korea, Sri Lanka, Thailand, and Tunisia. New programs utilizing spermicides may soon start in Nigeria, Peru, and Sudan.

Spermicide users comprise only a small segment of contraceptors in the developed countries—not more than five percent—and an even smaller segment in the developing countries. Use is highest in Latin America, where World Fertility Survey data from Colombia, Costa Rica, the Dominican Republic, Mexico, Panama, and Peru show that about 1 to 3 percent of exposed women are using spermicides. In Africa, spermicides are widely distributed

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in Ghana but very little elsewhere. Use in Asia appears to be minimal. Nevertheless, there is evidence that foaming tablets and suppositories are becoming more popular in both developed and developing countries.

The appropriateness, convenience, and acceptability of spermicidal methods must be judged by each user, taking into account her own circumstances. As an introduction to modern family planning, vaginal methods can be used as the logical next step from traditional methods, such as herbs and douches, already used in many cultures. If a male partner will not use condoms, use of spermicides provides a female alternative. Similarly, spermicides can be used temporarily when other methods are not available, for example after orals have been forgotten for several days, after an IUD has been expelled, or for the first few months after vasectomy. In fact, spermicides are often chosen not so much because of the advantages they offer as because of the disadvantages users see or fear in other methods.

Two major disadvantages limit the use and usefulness of spermicides: first, they must be applied shortly before each act of intercourse, a serious deterrent for women who are inhibited, lack privacy, or have uncooperative partners; and, secondly, they have higher failure rates than sterilization, orals, IUDs, or condoms. In fact, among US women using contraception surveyed in 1976, about 15 percent of spermicide users became pregnant within the first 12 months of use, compared with 2 percent of pill users, 4 percent of IUD users, and 10 percent of condom users (199).

Effectiveness Debated

Evaluating the effectiveness of spermicides is difficult since the major problem is not a failure of the product itself but a failure of the user to apply the product correctly and above all consistently. Studies show that patients in small clinical studies run by private physicians have lower failure rates—about one to seven pregnancies per 100 woman-years—than women questioned in nationwide surveys or women whose records are taken from hospitals or clinics—about 3 to over 20 pregnancies per 100 woman-years. On one hand, this may reflect the individual characteristics of these women—higher education, longer use, or stronger motivation. On the other hand, lower failure rates may also reflect greater care and effort on the part of the provider—to insure that women understand how to insert and use spermicides and that they appreciate the need for consistent, conscientious use. Differences among widely used formulations such as Delfen Foam, Emko, Conceptrol, Neo Sampoon, and Patentex Oval/Encare may be less than the differences among users or among providers.

Yet present spermicides are far from perfect. For the long run, research to identify longer acting, more effective, and more acceptable spermicides is in order. At present only a modest sum—approximately one million dollars annually—is spent for research on barrier methods, largely by commercial firms, and no promising new spermicides are in sight. For the short run, instructions, packaging, person-to-person counseling, and promotion could be much improved with relatively little cost and effort.

At present the role of the distributor or provider is crucial to both the acceptability and the effectiveness of vaginal contraceptives. While physicians and statisticians in developed countries may argue whether the failure rates of various new spermicides are 1, 5, or 15, health personnel in developing countries have to focus on their responsibility to contact and gain additional acceptors and to help them all use the most appropriate method in the most effective way. Program administrators must recognize that as more new acceptors are recruited through community-based or commercial efforts, failure rates will probably also go up. Nonetheless, giving spermicides their place beside other methods may fill the special needs of certain women and provide contraception for some who otherwise would do without.

End of Summary

HISTORY

Vaginal contraceptive preparations are among the oldest and simplest of all techniques to prevent conception. Egyptian papyri dating back to about 1850 BC offer the first written instructions for vaginal contraceptives, made with honey and natron (native sodium carbonate), and for various types of irrigating, plugging, and gummy substances to insert in the vagina before coitus. Prescriptions of a mixture containing animal dung—either crocodile or elephant—first appear in the ancient papyri and continue to be mentioned by writers in the Mediterranean area over a span of 3,000 years (84). From ancient Egypt to the present, various substances, often highly acidic, with pastelike or sticky bases, have been employed as vaginal contraceptives. Since highly acidic substances immobilize sperm, some of these primitive combinations may well have had some effect in reducing fertility.

Not until the late 19th century, however, did vaginal contraceptives emerge from folklore and ancient medical texts into the realm of everyday use. In England, the 1881 trial of Charles Bradlaugh and Annie Besant, for reprinting a pamphlet advocating douching, publicized, more than any deliberate advertising could have, the fact that simple vaginal methods of contraception were available and could be used without consulting the disapproving medical profession. The impact of the Bradlaugh-Besant trial is best indicated, as Norman Himes pointed out, by sales of the pamphlet, which jumped from a thousand copies annually before the trial to 185,000 copies in the 3½ years following (84). In fact, despite the opposition of the medical profession, the last two decades of the 19th century saw a tremendous expansion in the manufacture, advertising, and marketplace and mail-order distribution of a profusion of contraceptive methods. As John Peel points out, "With the exception of the oral contraceptive, there is not a single birth control method in existence today which was not already available and available in greater varieties in 1890" (137).

Among the first of the commercial spermicidal products were the quinine pessaries developed by Walter Rendell, an English pharmacist, in 1885. These suppositories consisted of soluble cocoa butter plus quinine sulfate, a common drug of the time but not, it later became known, a very potent spermicide. In most of the numerous early chemical spermicides, quinine sulfate was the active ingredient. Chinosol, lactic acid, and boric acid were also utilized, commonly with a cocoa butter or gelatin base (138).

In the total absence of scientific testing or government regulations, many formulations were ineffective and some, in strong doses, were irritating to the users. Nevertheless, they provided for the first time commercial contraceptive methods within the means of all but the poorest British and American families.

As early as the 1920s, scientific research on spermicidal methods was initiated (138, 156). The US National Committee on Maternal Health hoped to develop a vaginal contraceptive that could serve as "an effective germicide for the spirochete and the gonococcus—in other words a spermicide combined with a prophylactic for venereal disease." These hopes are still not entirely realized, but this research, funded by US organizations but undertaken in England, was one of the first scientific efforts to evaluate and improve any type of contraception (138).

An important innovation in spermicidal methods was the use of the effervescent tablet, which foams when it comes into contact with moisture, as a spermicidal preparation.

Figure 1. The brands of spermicides available on commercial markets are many. The forms of spermicidal contraceptives and the inert ingredients they contain vary considerably, but most products rely on a single active ingredient, nonoxynol-9.

First available in the 1920s, this was a development of the German pharmaceutical industry (138).

A further important improvement in technology was the introduction in 1937 of phenylmercuric acetate (PMA) as a spermicide, in the product Volpar. Even if recent concerns about the safety of mercury have since virtually banished mercuric compounds from the US market, PMA offered greater spermicidal effectiveness than such substances as quinine sulfate.

While spermicides were somewhat improved during the early twentieth century, the technological development of condom manufacture proceeded even faster. Advances in the use of latex rubber permitted the cheap mass production of thin yet strong condoms. Since the condom was recognized as a prophylactic against venereal disease and an effective contraceptive, its use generally surpassed that of the spermicides, many of which were overpromoted and failed to live up to the expectations of manufacturers and users.

The next important technological advance in the history of spermicides was the introduction of surfactants, or surface active agents, in the 1950s. Acting primarily by disrupting the integrity of the sperm membrane, surfactant spermicides are not strongly acidic and are rarely irritating to the vagina or penis. They are now the principal active ingredient in spermicidal products. They have been combined with different bases in a variety of forms, including jellies, creams, suppositories, foaming tablets, and foams in pressurized containers (see Table 1, p. H-106). Spermicidal contraceptives now sell on the commercial market at prices ranging roughly from $.10 to $.40 (US) per dose, the price depending more upon the brand and the place of sale than upon the form.

Contraceptive foams in pressurized containers, commonly called aerosols, first appeared in the late 1950s. They are usually applied by filling an applicator, like that used for jellies and creams, from the pressurized can. In the early 1970s, the Emko Company introduced applicators that could store a single dose for up to seven days and a combination container-applicator that holds six premeasured doses. Foams disperse well in the vagina (98) and, like jellies and creams and in contrast to foaming tablets and suppositories, they require no waiting between application and coitus.

In the last few years, attention has returned to suppositories and foaming tablets. The major international producer of foaming tablets is the Eisai Company, a Japanese firm, which markets Neo Sampoon loop foaming tablets, with a relatively new surface active agent, p-methanylphenyl polyoxyethylene (8.8) ether, commonly known as TS-88 or menfegol. They sell in tubes of 20 for about $.10 (US) per tablet. Eisai has vigorously promoted Neo Sampoon tablets in many parts of the developing world, and they are now gaining in popularity. This commercial promotion has sometimes paved the way for family planning programs supplying spermicides. Ortho Pharmaceutical Corporation holds the license for Neo Sampoon in the US, but Ortho has applied to the US Food and Drug Administration for new drug approval, which requires a review of safety and effectiveness. Therefore marketing of the product in the US is not expected soon.

In West Germany, Patentex GmbH has recently developed a solid product that, according to the manufacturer, both melts and foams. The Patentex Oval, or Encare, as it is known in the US, is being vigorously promoted despite controversy over early advertised claims of high effectiveness (see box, p. H-92). The product sells in the US for about $.35 per suppository.

Another innovative vaginal contraceptive is the water-soluble film known as C-Film. Originally developed in Hungary, C-Film is licensed for manufacture and sale by several companies in developed countries. As with many spermicides, clinical trials have produced mixed results (135, 174), and the effectiveness of C-Film remains in doubt.

The history of vaginal contraception is essentially a history of small improvements and marginal advances. Although family planning experts hope that further research will produce a more effective product, presently the extent of use of spermicidal methods appears to depend less upon marginal improvements in the product itself than upon vigorous promotion, wider availability, lower costs, and a more active effort to encourage consistent use.

USAGE

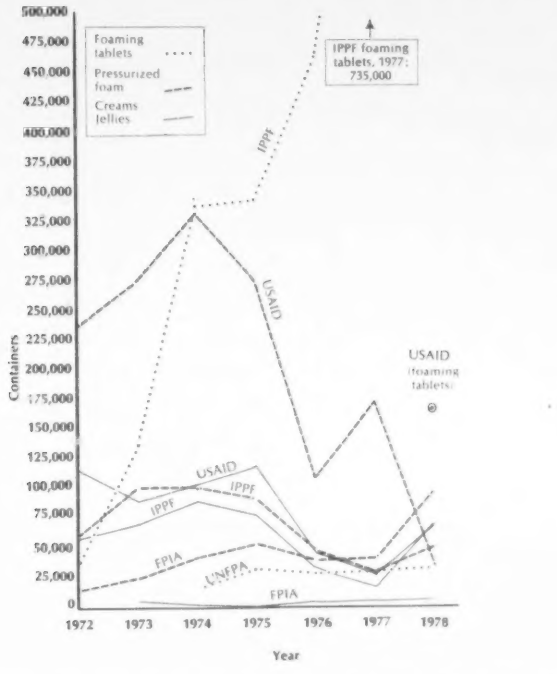
Neither in developing nor in developed countries do more than a small percentage of all contraceptors use spermicides. There is, however, some evidence that use of foaming tablets may be on the rise. In the developed countries, where spermicides are widely available through commercial outlets, the low usage rate may largely reflect user preferences. In developing countries, the even lower usage rate relative to other methods probably also reflects availability, since spermicides are not supplied in large quantities by most international donor agencies. (But international shipments partly reflect demand, and thus the two cannot be completely separated.) Many of the international supplies have gone to social marketing or community-based distribution programs for which spermicides, like condoms and oral contraceptives, are particularly appropriate.

The experience of Ghana indicates that spermicides might find more use in developing countries. For the past few years Ghana has been the major recipient of spermicides from international donors. In 1977, enough spermicides were either supplied to or distributed by Ghanaian family planning programs to provide roughly 65,000 couple-years of contraception.

Developing Countries

Shipments from international donor agencies suggest that Latin America has the highest proportion of spermicide users in the developing world. Africa ranks second, with Asia clearly third. In no country in the world are spermicides filling the contraceptive needs of a substantial portion of the population. Worldwide, the use of pressurized

Figure 2. Donor Agency Deliveries of Spermicidal Contraceptives, by Product Type, 1972-1978



Note: For data on which this figure is based, see Table 2-5, pp. H-110–112. UNFPA foaming tablet purchases in 1977 incomplete due to outstadning purchase orders.

Source: FPIA (140), IPPF (36, 94, 177), UNFPA (12), USAID (196)

foams, jellies, and creams has been fairly constant over the past decade, but the use of foaming tablets appears to be increasing.

Estimating distribution and actual use of spermicides is difficult. Spermicides are sold without prescription and therefore are not easily monitored except by manufacturers and commercial distributors, who do not make public their sales figures. Surveys of contraceptive use yield the best data because they include all users, whether supplied by commercial sources or by family planning programs. Such surveys are infrequent, however, and often, as in the World Fertility Surveys, spermicide users are so few that they are included in a single category with users of diaphragms and, sometimes, douching. Inventories of acceptors or of products distributed in family planning programs indicate roughly how many people are served through these channels, but trends are difficult to detect in supplies data because programs often take in a large stock one year and distribute it over several years.

The major donor agencies that distribute spermicides are the US Agency for International Development (USAID), the International Planned Parenthood Federation (IPPF), and Family Planning International Assistance (FPIA). In comparison with oral contraceptives, IUDs, and condoms, spermicides are supplied in small quantities. For example, in 1977 USAID supplied over 92 million cycles of oral contraceptives, or 7.1 million couple-years of contraceptive protection (see **Population Reports**, Series A, Number 5, *OCs—Update on Usage, Safety, and Side Effects*, January 1979); the total protection provided by USAID-supplied spermicides in the same year, assuming 100 acts of coitus per year (202), was less than 9,000 couple-years (see Table 2 and Figure 2; for Tables 2-6, see pp. H-110–114).

Deliveries of foams, jellies, and creams by USAID and FPIA, both of which handle requests for supplies made through USAID country missions, peaked in the mid-1970s. In the 4-year period between 1971 and 1974, the two organizations supplied about 940,000 containers of foam in 90-gram units or equivalent, half of it in 1974 alone, and 368,000 tubes of jellies and creams. In the subsequent 4-year period, 1975 to 1978, the figures were 879,000 for pressurized foams and 261,000 for jellies (see Tables 2 and 3). The number of countries receiving these spermicides has also declined from more than 35 in 1974 to fewer than 20 in 1978.

In 1978 USAID shipped a large quantity of Neo Sampoon foaming tablets to seven countries for research purposes (see Table 2). A total of 55,000 20-tablet tubes or equivalent went to new social marketing programs in Ghana, Sri Lanka, and Egypt, where they will be sold at a reduced price. Some 25,000 tubes or equivalent went to community-based distribution programs in Thailand, and 33,000 went to operations research projects in Tunisia, Korea, and Ecuador.

In recent years IPPF deliveries of spermicides have varied from year to year (see Table 4). Most shipments have gone to Latin American countries. Costa Rica, Colombia, Ghana, and Guatemala were the major recipients of jellies in 1978; Tanzania, Pakistan, and Nicaragua, of pressurized foams; and Ghana, the Philippines, Colombia, and Nicaragua, of foaming tablets.

Recently the United Nations Fund for Population Activities has supported purchases of Neo Sampoon foaming tablets requested by developing countries (see Table 5). The quantities are small—only 32,650 tubes for 12 countries in 1978. Mauritius has been the major recipient, receiving 15,000 tubes in 1978.

Data on program distribution collected by IPPF affiliates since 1975 show that the use of foaming tablets more than doubled between 1975 and 1977, the last year for which data are available, when 6.3 million tablets were distributed (see Table 6). The largest single user of foaming tablets in this period was Ghana, and use there grew faster than in the rest of the world. In 1977 the Ghanaian National Family Planning Association distributed 160,000 tubes of Neo Sampoon foaming tablets—half of all tablets distributed by IPPF affiliates around the world. Use of IPPF foaming tablets in Ghana may have peaked in 1978 at 200,000 tubes (53). Excluding Ghana, Latin America was the major area where tablets from IPPF were used. Latin American use increased dramatically in two countries, but on different scales. In Colombia, use of foaming tablets increased fivefold between 1975 and 1977, to 80,000 tubes. In Guatemala, use increased eightfold in the same period, to over 8,000 tubes. Use of pressurized

foams distributed by Profamilia, the Colombian IPPF affiliate, also increased, from 4,200 containers in 1975 to 12,000 in 1977. Substantial increases of this sort seem to result from the decisions of family planning programs to promote spermicides (88). On a worldwide basis, use of IPPF-supplied jellies and pressurized foams remained constant. Assuming 100 applications per year, in 1977 all IPPF-supplied spermicides provided over 100,000 couple-years of contraception in 60 developing countries.

World Fertility Surveys provide information about spermicide use in developing countries that includes purchases from commercial sources as well as distribution by family planning programs. Currently, data are available from six Latin American and nine Asian countries. While the data do not distinguish between spermicides and diaphragms, presumably most of the users are employing spermicides alone, since these are far more available than diaphragms, which require fitting, usually by trained personnel and in a clinical setting.

The World Fertility Survey data confirm the impression given by program and supply statistics that use of spermicides is slight. The proportion of currently married women exposed to the risk of pregnancy who use female local methods—that is, spermicides or diaphragms—ranges from virtually nothing in many of the Asian countries to roughly 3 percent in some Latin American countries (see Table 7). As might be expected, in most countries contraceptive users who are spacing births are more likely to use spermicides than those who want no more children.

Other recent survey data from Latin America show 2.1 percent of contraceptors in Costa Rica using vaginal methods, including spermicides (48), 3.7 percent in Mexico using female barrier methods or douche (47), and 1.9 percent in Paraguay using spermicides (8). In all three countries, spermicide use was more prevalent among contraceptors in urban areas than in rural areas; in fact, the smaller the city, the less spermicide usage as a percentage of all contraceptive use. This pattern may reflect the greater availability of spermicides in urban areas. It suggests that a market for spermicides could be developed in rural areas if products were available.

Lowering the price of spermicides or making them more widely available free of charge might increase their use (71). In a 1978 survey in Costa Rica, 77 percent of women who had used vaginal contraceptives reported having paid for them, compared with 18 percent of oral contraceptive users and 29 percent of IUD users (48). These figures raise the possibility that, in Costa Rica at least, programs providing free contraceptives did not meet the demand for spermicides as well as they did the demand for IUDs and pills.

Developed Countries

Once a major method of contraception in a number of developed countries, spermicides lost their popularity in the 1960s when more convenient and effective methods—the pill and the IUD—became available. Now, in most industrialized nations for which survey data are available, only from 1 to 3 percent of married women are using spermicides (see Table 8). While the percentages are small, the number of users is substantial. For example, the 3 percent of married US women using spermicides amounts to 825,000 women (146).

Table 7. Current Use of Female Local Methods, Including Spermicides, by Currently Married Women Exposed to Risk of Pregnancy in Developing Countries with Published World Fertility Survey Reports

Country & Year	Ref. No.	Of currently married exposed women, % using female local method[a]			Of currently married exposed women using contraceptives, % using female local method[a]		
		Total	Want more children	Want no more children	Total	Want more children	Want no more children
ASIA & PACIFIC							
Bangladesh (1976)	15	0	0	0	0	0	0
Indonesia (1976)[b]	90	0.4	0.2	0.6	1.1	0.8	1.1
Korea, Rep. of (1974)	107	0.4	0.2	0.4	0.9	1.2	0.7
Malaysia (1974)[c]	116	0.2	0.1	0.4	0.5	0.3	0.8
Nepal (1976)	129	0	0	0	0	0	0
Pakistan (1975)	133	0.2	0	0.5	2.7	0	3.3
Sri Lanka (1975)	180	0	0	0	0	0	0
Thailand (1977)	37	0.1	0	0.2	0.2	0	0.4
LATIN AMERICA							
Colombia (1976)	41	2.8	2.7	2.9	5.4	5.9	5.2
Costa Rica (1976)	49	2.1	2.2	1.7	2.7	3.1	2.0
Dominican Rep. (1975)[c]	57	2.8	2.9	2.8	6.8	11.7	4.9
Mexico (1977)	122	1.9	1.8	1.9	4.6	5.3	4.0
Panama (1976)	134	2.1	2.7	1.8	3.2	5.3	2.4
Peru (1977)[d]	156	1.1	1.1	1.2	2.7	3.0	2.6

NA = not available
[a] Female local method includes spermicides and intravaginal mechanical barriers
[b] Female local methods reported together with injection
[c] Douche included in female local methods
[d] Weighted sample

Table 8. Spermicide Use in Selected Developed Countries, as Reported in National Surveys, 1972-1977

Country	Ref. No.	Year	Population Surveyed	% of population surveyed currently using spermicides
Belgium	40	1975-1976	Currently married Dutch-speaking women aged 16-44	1
England & Wales	35	1975	Mothers and ever-married women aged 16-40	1
Italy	60	1976-1977	"People" aged 18-64	3
Japan	115	1977	Currently married women aged less than 50	6*
Poland	139	1972	Currently married women aged 16-49	
			Urban	3
			Rural	2
USA	65	1976	Currently married women aged 15-44	3

* Ever-use

With an estimated 5 percent of all women of reproductive age using spermicides (149), the Federal Republic of Germany probably has the highest usage rates in the world. This may be attributable to the active promotion in Germany of the Patentex Oval, which was introduced in 1973 and by 1978 had captured an estimated two-thirds of the spermicide market (85).

In the US, industry sources, while unwilling to divulge sales figures, report that sales are growing (13, 62, 194). Also, US family planning clinics saw requests for both foams and diaphragms grow modestly in the mid-1970s. In the 1972-1974 period, an average of 3.9 percent of clinic clients used foams; in 1975, 4.8 percent; in 1976, the most recent year for which data are available, 5.6 percent (191). No similar trend has been seen in US national survey data, however (see Table 9). In the most recent survey, conducted in 1976, foams, diaphragms, and rhythm were roughly equal in current usage by married women, behind the more effective methods of oral contraceptives, male and female sterilization, condoms, and IUDs, but ahead of the less effective methods, withdrawal and douching (64, 65). Slight changes in proportions between 1973 and 1976 among methods other than the pill should be interpreted cautiously because of the small numbers of survey respondents involved (65).

Because spermicides are used only at intercourse and are easily available through commercial channels, they are particularly convenient for young women who have intercourse infrequently (44). Reportedly these reasons help explain why spermicides are especially popular with young, unmarried women in West Germany (149). Young US women, in contrast, have not especially favored spermicides. In 1976, only 3.6 percent of unmarried women under age 20 with contraceptive experience listed spermicides as the most recently used method (166, 214), about the same percent as among married women (65).

ACCEPTABILITY

Acceptance of a contraceptive method rarely hinges on one characteristic; usually a whole cluster of characteristics affect use (163). The traditional view that use of vaginal products depends entirely on the product and on the motivation and conscientiousness of the user is now being questioned. Recent experience from a wide range of programs suggests that popularity and use of most contraceptive methods, including spermicides, can be influenced substantially by the actions and attitudes of family planning providers.

The Role of the Provider

The role of spermicide providers deserves attention but is often overlooked. These providers include both the commercial and community-based organizations which package, distribute, and promote spermicides and the health personnel who dispense them from clinics. Of the two, the nonmedical sources probably play a larger role in stimulating acceptance, but their activities are rarely discussed in medical or scientific publications unless a controversy develops.

Manufacturing and/or distributing organizations are responsible for insuring the easy availability of spermicidal products which, in most countries, can be sold without prescription or other medical intervention. They are also usually responsible for advertising and other promotions if legally permissible. Japan and West Germany provide good examples of the role commercial firms can play. In Japan an extensive promotional campaign for Neo Sampoon took place in the 1950s. The proportion of couples using contraception began to increase rapidly at that time and, even today, use of the tablets is greatest among women in their 40s. These older women, despite the greater sexual inhibitions of the older generation (10), chose tablets as their contraceptive at the time of the campaign (123, 126). When 671 German users of

Table 9. Contraceptive Methods Used by Currently Married Contracepting Women Aged 15-44 in the United States, 1973 and 1976

Method	Percent 1973	Percent 1976
Pill	36.1	32.8
Contraceptive sterilization, male	11.2	14.3
Contraceptive sterilization, female	12.3	14.1
Condom	13.5	10.6
IUD	9.6	9.0
Rhythm	4.0	5.0
Foam	5.0	4.4
Diaphragm	3.4	4.3
Withdrawal	2.2	2.9
Other	1.9	1.3
Douche	0.8	1.0

Source: Ford (65)

Figure 3. A group of Mexican women chose the design at left for spermicide package labeling used in the Mexican PROFAM social marketing program because the position of the circle communicated to them a "protective contraceptive meaning." By contrast, they took the design at upper right to symbolize a product for the whole family and the one at lower right to suggest a product to promote fertility. Also, the women selected aqua blue as the most attractive background color for the package. (PIACT de Mexico (148)

Patentex Ovals who had become pregnant and were surveyed in the Netherlands when they sought abortions were asked why they had chosen the product, 27 percent of the responses cited "advertising" and 19 percent, "easy availability." (Multiple responses were given.) In other words, a major stimulus for using Patentex Ovals stemmed from the actions and policies of the manufacturer (149). It is estimated that about 3 percent of German women are using Patentex Ovals, even though the product was only introduced in 1973 (149).

In the developing countries also, advertising and promotion have an impact on the acceptability of spermicides. In Colombia, for example, Neo Sampoon tablets were at first distributed without advertising, through a retail system operated by Profamilia, an affiliate of the International Planned Parenthood Federation. In 1978 Eisai, the manufacturer of Neo Sampoon, sponsored three months of one-quarter page advertisements in three major women's magazines. Sales of the product by Profamilia approximately quadrupled (52).

Another example of vigorous promotion techniques comes from Bangladesh, where Population Services International (PSI) has begun to market Neo Sampoon tablets under the brand name "Joy," with attractive packaging and advertising displays printed in Bengali. A 1979 marketing campaign was designed to sell 4,000 tubes in three months from 31 outlets in Dacca and Chittagong. As a result of effective advertising that described the product and its use, within two months nearly all the stock was sold out and vendors reordered another 3,000 tubes (7). PSI is not a commercial firm but rather a private, nonprofit agency, funded by the US Agency for International Development. PSI applies the methods of a commercial entrepreneur to contraceptive distribution.

Spermicides are also gaining in acceptability through innovative community-based distribution programs as well as through the variety of social marketing approaches, like that in Bangladesh, which have sprung up in recent years. The nationwide contraceptive education and commercial distribution program in Mexico, Programa de Educación y Distribución Popular de Productos Anticonceptivos (PROFAM), is distributing contraceptive suppositories made by Norwich Mexico and both a cream and a pressurized foam made by Lemery. Activities began in March 1979, and an estimated 18,000 outlets will be supplied in the first year of operation (54). In Egypt, IPPF will support a commercial distribution program in which individually wrapped tablets will be sold at drugstores under the trade name "Amaan" (52).

Packaging is important to product acceptability. PROFAM, with the help of the Programa para la Introducción y Adaptación de Tecnología Anticonceptiva (PIACT de Mexico), has carried out market research in order to devise a symbol for use on packaging that will insure correct identification and high acceptability for various contraceptives, including foam, cream, and suppositories, and will inspire confidence in the products. Discussion groups composed of Mexican women, both contraceptive users and nonusers, reviewed the stylized man and woman figures used as the PROFAM symbols, as well as different colors for the design. Figure 3 shows the alternative designs for female contraceptive packages. When the white circle was placed on the woman's abdomen, it was taken as a symbol of pregnancy, suggesting medicine to enhance fertility. Its absence vaguely suggested products for all members of the family. When the circle was placed on the lower edge of the woman's skirt, participants said that it elicited a "protective contraceptive meaning." The most appropriate color for the spermicidal cream and foam packages was found to be aqua blue, which evoked feelings of freshness (148).

Despite the value of advertising in increasing public acceptance, legal obstacles in both developed and developing countries stand in the way of full promotional efforts. Television advertising of barrier methods, for

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example, is forbidden in the United States and the United Kingdom.

Spermicides are marketed as feminine hygiene products in some countries where it is illegal to advertise contraceptives or where the manufacturers and the lay press have assumed that social and political conditions are unfavorable for the promotion of contraceptives. In Brazil, for example, spermicide products can be marketed only as feminine hygiene products, and in some countries of Francophone Africa contraceptive suppository packages contain instructions for use but no indication of their purpose (154).

Despite a few exceptions and the pioneering work of a handful of social marketing projects, however, most commercial spermicide manufacturers and distributors take a conservative approach to marketing. In a recent survey by Business International of contraceptive distribution operations in eight developing countries, one executive of a firm that manufactures oral contraceptives, condoms, and spermicides remarked:

> We are undoubtedly the most highly regulated industry and we manufacture products that continue to be controversial. If we are careful in our marketing, even unimaginative, it should not be difficult to understand why (32).

Manufacturers face a real dilemma. On one hand, where use of spermicides is low and commercial infrastructure in rural areas is lacking—as in Morocco, Nigeria, and Indonesia—manufacturers point out that public sector education about family planning is necessary before they can promote specific products. In any case, they note, the cost of products is too high for most of the population. On the other hand, in countries where spermicide use is greater and promises to increase—as in Costa Rica and the Dominican Republic—extensive government promotion and distribution programs are underway and manufacturers anticipate that free or subsidized government-supplied spermicides will destroy the market for commercial sales. Already in the Dominican Republic, women obtain spermicides free from government clinics, then sell them for $.50 to $1.00 to pharmacies (about one-half the wholesale price), and the pharmacies resell them at a profit (32). Even in Korea, where a local manufacturer advertises widely and sells about half a million 10-unit packages of spermicides annually, cooperation between the manufacturer and the government is not close. Government agencies regulate the industry, prohibit imports of contraceptive products, tax the raw materials required, and have tried to buy the product at a price that the company considered unprofitable (32).

The role of health care personnel—either private physicians or clinic staff—who recommend and/or dispense spermicides together with other contraceptives can also be important to the acceptance of these products. Spermicides appear so simple that a trained provider is not necessary, but if health care personnel take a negative attitude toward barrier methods, they discourage women who might prefer a local or occasional method or who would find spermicides a useful back-up to another method.

The importance of health care personnel is evident from multicenter clinical trials which find that complaints about side effects vary greatly from one center to another. In a study in Manila, one clinic experienced only about half as many complaints and one-fifth as many discontinuations for side effects as two other clinics (63). In Colombia, Guillermo Lopez and colleagues report, complaints at one Bogotá clinic were nearly twice as frequent as at another (114). In Guatemala, Luis Galich has observed that when medical and paramedical personnel are familiar with Neo Sampoon, demand for the product increases (70). When health personnel inform acceptors in advance, for example, that spermicides will provide additional lubrication and that foaming tablets may generate a feeling of warmth, the effects can be depicted as benefits rather than disadvantages.

Figure 4. The old, cautious approach to marketing spermicides in Latin America contrasts with the new. The advertisement at left labels the contraceptive Lorophyn a feminine hygiene product only but tells the user to wait ten minutes for the suppository to disperse and to refrain from douching for six hours—instructions like those for most other contraceptive suppositories. In 1978, the same manufacturer began advertising its products in women's magazines in Guatemala, El Salvador, Nicaragua, and Honduras with the forthright declaration shown at right: "Yes. Norforms is a contraceptive."* (Norwich International)

*The product named Norforms in the United States is not a contraceptive.

It has been suggested that health care providers in the US are biased against barrier methods (44) and that many family planning workers have minimized their usefulness (23). Physicians may associate barrier methods with ineffective patent medications; they see couples for whom the method has failed and rarely encounter couples who acquire their spermicides through commercial outlets and use them successfully (143). A survey of family planning personnel in two US cities illustrates one way in which this bias operates. Respondents tended to rate the pill and the IUD according to theoretical effectiveness whereas they rated foam according to use-effectiveness or even lower (193).

The impact of such biases is not negligible. Gerald Bernstein reports that women who become pregnant after IUD expulsion or after running out of pills sometimes comment that they did not use barrier methods in the interval because "the nurse told me they are not much good anyway, so I didn't bother" (23). At Bernstein's facility, a California teaching hospital, staff who offered such advice were given additional instruction. In the hospital's family planning program, all postpartum clients were given foam or condoms or both. Those who chose the IUD or pills also received a supply of foam or condoms to use in case they forgot to take the pills or could not return to the hospital quickly in the event of an IUD expulsion (23).

In contrast to the skepticism of some professional health personnel in the United States, increased interest in barrier methods is developing through the women's self-care movement. Judy Norsigian of the National Women's Health Network estimates that approximately 10,000 US women are now served by about 200 health collectives. Although most of these organizations provide all legal methods of family planning, they encourage the use of barrier methods and urge that women play an active role in attending to their own health and contraceptive needs (31).

Product Characteristics

The reason spermicides can be distributed relatively easily through a wide variety of channels is to a large extent dependent on the nature of the products themselves. They are relatively easy to understand, not difficult to use, and completely safe. Safety is an important factor since it not only appeals to the user but also permits many forms of nonmedical distribution. (For discussion of spermicide safety, see pp. H-96–101.) These qualities attract many women, especially first-time users. As one researcher noted at the recent Program for Applied Research on Fertility Regulation (PARFR) International Workshop on New Developments in Vaginal Contraception in Guatemala,

> The preference for Patentex Oval especially among young, unmarried women is understandable. Patentex Oval is freely available and preeminently suitable for women having infrequent intercourse. Patentex Oval might be considered a female equivalent for the condom, in terms of being a method for beginners (149).

Probably the most important spermicide characteristic determining long-term acceptability is the fact that spermicides must be used at the time of sexual intercourse. On one hand, this feature appeals to women who have sexual relations infrequently, because it means that they can avoid effort, expense, and risk accompanying methods that must be used constantly without regard to coital frequency. On the other hand, it does not appeal to women or men who are not willing to interrupt lovemaking or prepare immediately in advance. Where privacy is lacking, all barrier methods can be awkward to use.

Other product-related factors that influence and sometimes reduce acceptability are the various physical sensations caused by spermicides. For example, some preparations noticeably increase lubrication, leave a liquid residue, or emit an odor. In postcoital tests a few couples have complained that Patentex Oval generated so much foam that friction during intercourse was diminished (30).

Foaming solid spermicides generate heat when dissolving, which both partners are likely to sense. This heat-releasing effect apparently disturbs some users but not others. In the Makati Clinic in Manila, over one-third of the 129 users studied complained of a strong heat sensation, but only 7 either changed contraceptive methods or dropped contraception entirely as a result of side effects (63). In a Japanese study of 587 couples, however, only 15 women complained of local irritation and none were reported discontinuing for that reason (96). In another study, 32 of 56 Japanese couples experienced unusual warmth from the tablets for one or both partners; of these couples, however, only four felt the sensation uncomfortable, and none rejected the method because of it (131).

For some users, the sensation of heat is pleasurable. In Ghana, men buy the foaming tablet because "it has a burning sensation that stimulates a lot" (76, 79). From the male Ghanaian point of view, foaming tablets are cheap, they are easy to carry, they are not messy, and, unlike condoms, they apparently add to rather than detract from sexual pleasure. In Lesotho also, men enjoy the sensation of heat produced by Neo Sampoon (190). In the Philippines, advertisements now cite the sensation of warmth as an added benefit (114); T-shirts read "Neo Sampoon – for that warm sensation."

Perceptions of the User

How the user herself regards spermicides is the ultimate test of acceptability. In addition to the role of the provider and the characteristics of the product, different factors contribute to each user's reaction, including cultural background, individual sexuality, a male partner's reaction, and, apparently to an increasing extent, comparisons with other methods.

Everyone is influenced by cultural background. Throughout the world, the user's expectation of "what good medicine should look like" can be critical in determining whether any product is used (16). If the form in which a contraceptive is administered resembles an already familiar and trusted medication, prospective users may be more inclined to try it. In a 1971 survey conducted in Guayaquil, Ecuador, for example, more women expressed a positive attitude toward foam tablets than toward any other form of barrier contraception because they identified foam tablets as a type of suppository. In Ecuador suppositories are commonly used for administering medica-

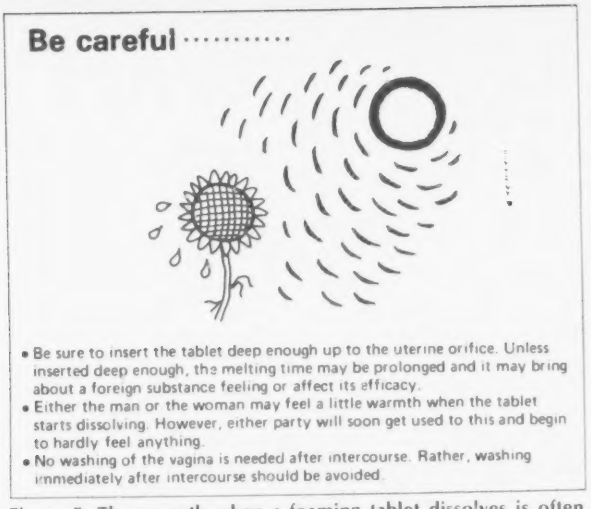


Figure 5. The warmth when a foaming tablet dissolves is often noticeable, but most couples become accustomed to it, as this Neo Sampoon brochure states. In some places—Ghana, for instance—the warmth is a selling point. (Eisai Company)

tions (163). In rural Egypt, where folk methods of vaginal contraception, including herbs, lemon juice, and aspirin, have been passed from generation to generation (184), one would expect modern spermicides also to be readily acceptable (43).

Individual attitudes toward sexuality also influence attitudes toward contraception, but the strength of such influences is unclear and deserves more systematic investigation. In Lee Rainwater's interviews of 50 US working-class women and 45 men, he found that women who disliked sexual activity were more likely to dislike the consistent, active participation in contraception that vaginal methods require (150). Women who dislike touching their genitals would probably also dislike using spermicides.

Attitudes do change, however. Susan Scrimshaw suggests that in some culture groups such as Guatemalan Indians, women are not likely to accept vaginal contraception because of their strong dislike for touching their genitalia, but she also notes growing use of menstrual tampons among Hispanic groups in Latin America, who previously displayed a similar reluctance (163).

The male partner's attitude is also crucial since it is difficult for a woman to use vaginal contraceptives without his acquiescence (163). A husband may dislike his wife's advance preparation, signaling her expectation of intercourse. In Colombia, such dislike appears to be more prevalent among lower class couples (114). When solid spermicides are used, if a man is unwilling to wait for the suppository to melt, a woman is not likely to persist with the method.

Another factor that is increasing the acceptability of spermicides, diaphragms, and condoms is the anxiety some women are beginning to feel about the safety of the more effective methods such as pills and IUDs (14, 31, 44, 178). Even though these fears may be exaggerated, media publicity about the hazards of modern methods, especially oral contraceptives, has unquestionably made some women reluctant to use them. For example, one-third of the reasons for using Patentex Ovals listed by the 671 West German women seeking abortions in the Netherlands were in some way related to the pill; 18 percent cited "an antipill attitude," 14 percent cited using the spermicide during a pause in OC use, and 1 percent cited "pill complaints" (149). More than 50 percent of the "pill pause" group and about 20 percent of the "antipill attitude" group became pregnant within three months of use whereas the average was nine months (149). Although these data represent a specific subgroup of German women—using spermicides, becoming pregnant, and choosing to have an abortion in the Netherlands—they do suggest that women who shift from oral contraceptives to spermicides are especially vulnerable to unwanted pregnancy. At the same time, the availability of safe, legal abortion probably increases the willingness of some women in developed countries to use methods like spermicides that do have higher failure rates but that present no risk of systemic effects or other health hazards.

In the developing countries also, reluctance to use the pill, whether for health or other reasons, has been cited as a reason for the increasing use of spermicides. Such reports come from Bangladesh (161), Colombia (114), Costa Rica (32), the Dominican Republic (32), Guatemala (70), and South Korea (32). An executive of a Korean spermicide manufacturing firm, for example, admitted that the popularity of the spermicide was due as much to the deficiencies of other contraceptive methods and products as to the quality of his firm's products (32). He mentioned five reasons for the success of the products in Korea: (1) The public is aware of and has read articles on the findings of international groups on the possible linkage of hormonal contraceptives to heart disease and cancer. (2) Family physicians caution their female patients against using oral contraceptives. (3) Older women fear using orals. (4) Some women who will not take oral contraceptives are also unable to use an IUD. (5) Many people do not like to use condoms. In Costa Rica, the business manager of a firm that distributes various pharmaceutical products noted that among married couples, spermicides are far more popular than condoms since condoms are still associated with illicit sexual relations and prostitutes (32).

Recognizing that acceptability of a contraceptive method may be more strongly influenced by the perceived disadvantages of other methods than by the advantages of the method selected, firms that advertise spermicides often call attention to these disadvantages rather than to the specific benefits of the spermicide (see box p. H-92).

MEASURING EFFECTIVENESS

The major drawback of spermicides is the high failure rate often seen in actual use. Although a battery of laboratory tests shows that most spermicides do immobilize sperm, clinical studies and user surveys yield failure rates from as low as 0.3 pregnancies per 100 woman-years of use to as high as nearly 40, depending on the products used, the populations tested, and the type of instruction and support that is provided. (For a comprehensive review of earlier studies on spermicide effectiveness, see **Population Reports**, Series H, Number 3, *Vaginal Contraceptives: A Time for Reappraisal?*, January 1975.)

Today a renewed effort is underway to analyze all of the reasons for spermicide failure in order to identify the best ways to reduce failure rates in actual use. Gerald Bernstein and Robert Nakamura have identified three types of contraceptive failure applicable to spermicides that can be tested and evaluated independently:

- physiological (or method) failure, in which the product did not protect against pregnancy even though it was used correctly and consistently;
- psychological (or user) failure, in which the contraceptor failed to use the product at all or used it incorrectly despite adequate instructions; and
- procedural (or provider) failure, in which the contraceptor used the product incorrectly because the provider did not supply full and accurate guidance (24).

Table 10. Melting Time, Duration of Effectiveness, and Time before Douching Is Permissible, for Spermicidal Contraceptives, As Recommended in Manufacturers' Package Labeling and Package Inserts

	Time required to melt (in minutes)	Duration of effectiveness (in hours)	Time before douching is permissible (in hours)
FOAMING TABLETS			
Antibion	3-5	[a]	[b]
CCC	2-5	[a,c,d]	NS
Neo Sampoon	2-10	[a,c]	NS
Semori	3-4	[a]	NS
Speton	5	NS	1
SUPPOSITORIES & OTHER INSERTS			
A-gen 53	8-10	[a]	6-8
Agena	5	[a]	6
Encare (foaming)	10	[a,e]	6
Lorophyn	15	[a,e]	6
Norforms	15	[a,e]	6
Patentex Oval (foaming)	10	[a]	NS
Profam	10	NS	8
Rendells	3-5	[a,c]	6
Semicid	15	[a,e]	6
Si-O-Safety Oval	3	NS	NS
S'positive (foaming)	5-8	[a]	6
Ta-ro-cap	5	[a]	NS
JELLIES			
Agena		NS	NS
Patentex		[a,f]	NS
Ramses		[a]	8
CREAMS/PASTES			
Flavo-cept (raspberry)		[a]	[g]
Profam		[a]	[g]
PRESSURIZED FOAM			
Emko		[a,h]	6
Patentex		[a,f]	6-8
Profam		[a]	8
SOLUBLE FILM			
C-Film	3-5, 15[i]	[a]	[j]

NS = not stated on package label or package insert

[a] Initial dose must be repeated before each act of intercourse.

[b] "Douching after intercourse is not recommended. However, if desired, use warm water in which an Antibion tablet is dissolved."

[c] If intercourse lasts more than 30 minutes, insert a new tablet.

[d] If most of foam has leaked out or if ejaculation has occurred before tablet has dissolved, insert a new tablet.

[e] If intercourse has not taken place in one hour, insert a new suppository.

[f] May be inserted up to 30 minutes prior to intercourse.

[g] "Douching not necessary." Package insert does not state time interval required between completion of intercourse and douche.

[h] "Must be applied before physical contact but not more than one hour in advance."

[i] "Insertion of C-Film 3-5 minutes before intercourse will allow the film to dissolve. 15 minutes is probably ideal."

[j] "Douching is never recommended"

Product Effectiveness

Physiological, or method, failure is caused by shortcomings of the product itself, not of the user or provider. The physiological effectiveness of spermicides depends on two factors: (1) the potency of the active spermicidal ingredient and (2) the ability of the base, or vehicle, to spread rapidly and evenly over the cervical opening, to make the active ingredient chemically available, and to hold the spermicide in place as long as possible. The most recent effectiveness studies have focused on evaluating base materials and existing product combinations rather than active spermicidal agents alone.

Different types of spermicides vary in their ability to provide rapid and extensive coverage. Foams and creams are dispersed best, according to laboratory studies of human sexual activity (98). Suppositories need body heat to melt. Foaming tablets need moisture to produce foam, and distribution in the vagina may depend in part on coital movements. Thus, solid preparations may require as much as 15 minutes between insertion and coitus to insure melting or foaming action. (See Table 10.)

Spermicidal preparations vary both in the total amount and the concentration of active ingredient in each dose. Differences in total dose could influence effectiveness, perhaps especially so among women who produce large amounts of vaginal fluids (18). The only reported investigation of the effects of partial dosages is H. Brehm and J. Albrecht's postcoital tests of the Patentex Oval, in which application of one-half dose was effective but one-fourth dose produced less spermicidal action (29).

Since the quantity of vaginal fluid varies and since there are no standard tests to measure spermicide dispersal, studies of dispersion sometimes produce contradictory results. For example, the manufacturer of Patentex Ovals claims that the combined melting and foaming action of the product does not depend upon the amount of vaginal fluids (136). Yet, in one study foam was fully developed in all 55 users 10 minutes after insertion, whereas in another study little or no foam was generated in 9 of 20 women after 15 minutes, and the product was removed "almost intact" (183).

Furthermore, in all types of spermicides the chemical content of the base material may influence effectiveness both independently and in conjunction with the active spermicidal agent. In vitro tests of eight bases by A. Kassem and colleagues indicate that polyethylene glycol ointment allows maximum spermicidal activity for all of the active ingredients studied except phenylmercuric acetate, which performs best in a carbopol resin (99). Some bases themselves can immobilize sperm. The bases for Delfen Cream and Preceptin Gel, for example, immobilized

Table 11. Amount of Active Ingredient and Lowest Effective Concentrations for Six Vaginal Contraceptive Products in Sander-Cramer Test

Product	Active ingredient	Amount (in milligrams) of active ingredient per 100 mg	Lowest concentration of product in mg/ml capable of immobilizing sperm in 20 seconds*	Amount of active ingredient per 100 mg at lowest effective concentration (col. 3 × col. 4)
Delfen Foam	Nonoxynol-9	12.5	0.99 ± 0.0	12.4
Neo Sampoon Tablet	Menfegol	7.5	4.8 ± 0.1	36.0
Delfen Cream/Conceptrol	Nonoxynol-9	5.0	5.1 ± 0.1	25.5
Orthoforms	Nonoxynol-9	2.0	10.6 ± 0.3	21.2
Ortho-Gynol Jelly	Triton X-100	1.0	48.6 ± 1.4	48.6
Encare	Nonoxynol-9	2.3	100	230.0

Note: Tests conducted using six semen samples from the same six donors for each product
* Mean values ± standard error

Source: Hahn et al. (77)

human and rabbit sperm in one titration test, but the base for Delfen Foam did not (86).

The materials in the base may act as a physical barrier as well. In one slide test using the dissolved base for Patentex Oval without the active ingredient, the foam formed a barrier that human sperm could not penetrate (30). By contrast, commercial jelly used purely for lubrication had no effect on either sperm motility or fertility in a test with macaque monkeys (210).

Yet it is not clear from tests of different products how much the base material actually affects the potency of the final product. Sander-Cramer tests on six different products showed, for example, that a smaller amount of nonoxynol-9 was needed in Delfen Foam and Delfen Cream than in Orthoforms or Encare to achieve the same level of spermicidal effectiveness (see Table 11) (77). Preliminary results of a comprehensive series of tests by Richard Cone at the Johns Hopkins University suggested, however, that product effectiveness was directly related to the amount of active ingredient, regardless of the properties of the base (142).

The technology for examining in vitro spermicidal activity is being improved. One new testing apparatus, for example, allows simultaneous comparisons under the microscope of sperm motility in minutely different test compound concentrations (108). In vitro tests in addition to the Sander-Cramer and IPPF Agreed tests (see box, p. H-90) have been devised, the application of which depends upon the mode of action of the contraceptive. For example, a vaginal contraceptive that is supposed to promote resistance in cervical mucus to sperm transport should be tested utilizing human cervical mucus obtained at midcycle or a comparable animal cervical mucus (198).

In Vivo Testing

Because of the obvious limitations of in vitro tests, in vivo tests utilizing live animals or humans have also been devised. There are essentially two types of in vivo testing for vaginal contraceptives: postcoital examinations and fertilization tests.

In postcoital tests with animals and humans, samples of cervical mucus and vaginal fluid are examined for the presence of motile sperm at a specified time period after ejaculation. Unlike in vitro findings, postcoital test results can describe spermicidal action in the vagina. Samples of cervical mucus offer an indication of whether sperm have crossed the physical and chemical barrier created by the formulation studied. For animal tests, the rabbit (74) and the stumptailed macaque (210, 211) have been used. The most elaborate of postcoital tests in human females, conducted at the Masters and Johnson Institute in St. Louis, USA, in the 1960s, used a dildo to stimulate female sexual response, after which semen was deposited in the vagina, simulating ejaculation. These human studies are now being conducted again because of renewed interest in barrier contraception (106).

The disadvantages of postcoital tests are: (1) they are more elaborate and expensive than in vitro testing, especially when human subjects are involved and (2) their significance may be nullified by the speed and mechanisms of sperm transport.

For example, some sperm may reach the cervical canal within 90 seconds or less of ejaculation, that is, before any tests can be conducted (176); sperm may be stored and protected in the thousands of crypts along the walls of the cervix for later release; and sperm may be able to reach the ovum from the cervix even if not motile because of mechanisms in the female reproductive tract that assist in sperm transport (125). Thus, tests detecting only immotile sperm in cervical fluids may indicate that fertilization is unlikely but not that it is impossible (210).

Postcoital tests have been used to measure the effect of different intervals between the application of spermicides and coitus. West German and US tests of the Patentex Oval/Encare produced different results, however. In 44 German women having intercourse within the recommended period of 10 minutes to 2 hours after insertion of the spermicide, no motile sperm were found in the vagina, and no sperm at all at the external os in 40 cases and in the cervical canal at a depth of 1.5 to 2.0 cm in 44. In 3 cases where coitus took place less than 10 minutes after insertion and in 8 cases where coitus took place

Two Widely Used Spermicide Tests

In vitro tests typically involve the mixing of dispersed spermicidal products with samples of human semen in order to determine sperm-killing potency. The advantages of such tests are that they are simple to conduct, they permit direct observation of spermicidal activity, and they are inexpensive. The disadvantages are that they cannot measure a preparation's physical barrier to sperm and they cannot measure how well a spermicide is distributed in the vagina.

The two most widely used in vitro spermicide tests are the former IPPF Agreed Test for Total Spermicidal Power (95) and the Sander-Cramer test. They can be utilized to measure the effectiveness either of commercial preparations or of active spermicidal agents alone. The former IPPF Agreed Test furnishes a pass or fail verdict on a spermicide batch using a gram of spermicide diluted with 11 ml of .9 percent saline solution. One ml of this solution is mixed with 2 ml of human semen. Testing takes place in three steps. First, after 40 seconds of exposure to the spermicide solution, all sperm must be completely immobilized. Second, after 30 minutes of incubation at 35-37°C, the sperm must still reveal no signs of activity. Third, both of these results must be repeated with samples from different packages tested against the semen of two other donors (a total of three) or of five of six donors. Only then has the spermicide sample satisfied the test (95).

Such in vitro tests of spermicidal activity cannot be equated with effectiveness in actual use. Fearing that satisfying the Agreed Test would be misinterpreted as an IPPF endorsement of contraceptive effectiveness, the IPPF Central Council ordered the discontinuation of IPPF spermicide testing in November 1978 (102).

The Sander-Cramer test determines the weakest concentration of spermicide capable of immobilizing sperm within 20 seconds. In this test, .2 ml of human semen is treated with 1.0 ml of diluted spermicide. The spermicide is progressively diluted until the weakest dilution that completely immobilizes all sperm in 20 seconds is found (160).

more than 2 hours after insertion, no sperm at all were found within the cervical canal and only immotile sperm in the vagina and at the external os (28, 29, 30).

Artificial coitus tests conducted by William Masters and colleagues in the US, however, found that intervals from insertion to intercourse outside the range of 5 to 60 minutes markedly reduced the spermicidal efficacy of Encare. (They confined tests to the vagina because their 16 subjects wore cervical caps containing spermicidal jelly, primarily to protect against ascending infection.) When semen was deposited between 5 and 60 minutes after insertion of the suppository, 4 aspirations in 336 showed motile sperm in the vagina. In tests conducted with 30-second, 1-minute, and 3-minute intervals between treatment and semen deposition, however, motile sperm were visible in 83.3 percent, 52.1 percent, and 20.8 percent of the cases, respectively. The tests performed when intercourse occurred after 90 and 120 minutes showed motile sperm in 25 percent or more of cases (117). As a result of these tests Eaton-Merz Laboratories, US distributor of Encare, changed its advertised claim of effectiveness from two hours to one hour.

Animal fertilization tests use failure to impregnate as their end point rather than sperm immobilization, but fertility tests do not always agree with other measurements of effectiveness. Although postcoital tests of Delfen Cream showed complete sperm immobilization, two fertility tests with the same animals produced pregnancies in half within an average of 3.7 cycles (210). One set of tests of the contraceptive performance of Delfen Foam, Delfen Cream, and Preceptin Gel in rabbits showed a relative ranking consistent with the in vitro effectiveness of these preparations (86). In another set of tests, however, when seven commercial preparations were tested for potency both by Sander-Cramer tests using human semen and by in vivo tests of implantation rates in rabbits, rankings by relative potency did not correlate well in the two series, as shown in Table 12. The Patentex Oval, which was the least potent of the seven products in the in vitro tests, was the third most potent in the rabbit tests (87).

Laboratory studies like those described here can help researchers determine whether further investments in product development are warranted. Since no laboratory test presently used can take into account all factors that affect physiological effectiveness, however, it would be inappropriate to base the choice of a vaginal contraceptive on the results of such tests alone.

User Characteristics

While some vaginal products are probably more effective than others, some contraceptors are also more effective in using these products than others. Physiological, or method, effectiveness, is defined as the failure rate for persons who apply the method correctly. It is a more realistic indication of effectiveness in actual use than any laboratory studies. Two problems arise, however. First, users' reports of their own behavior may not be accurate, and second, there is no standard definition of correct use. Investigating whether spermicides are used correctly requires much more information than investigating whether methods such as the pill are used correctly (193). Perhaps for these reasons, method failure rates in clinical trials have varied, not only for the same type of spermicidal products, but even for the same brand of preparation (see **Population Reports**, Series H, Number 3, *Vaginal Contraceptives: A Time for Reappraisal?*, January 1975).

Table 12. Relative Potencies of Seven Spermicidal Products, as Determined by Sander-Cramer Tests and Rabbit Fertility Tests

Product	Sander-Cramer Test			Rabbit Fertility Test		
	Milligrams[a]	Relative Potency[b]	Rank	Milligrams[c]	Relative Potency[b]	Rank
Delfen Foam	1.0	1	1	2.3	1	1
Koromex II Cream	5.0	0.2	2	1,400	0.0016	5
Delfen Cream	5.0	0.2	2	390	0.0059	4
Orthoforms	5.7	0.18	3	120	0.019	2
Koromex II Jelly	20.0	0.05	4	[d]	[d]	7
Preceptin Gel	25.0	0.04	5	2,800	0.0008	6
Patentex Oval/ Encare	100.0	.01	6	149	0.015	3

[a] Minimum dosage per ml capable of immobilizing human sperm within 20 seconds
[b] Most potent assigned a value of 1
[c] Dosage capable of reducing implantation rate to half that of the control series (ED_{50})
[d] No dose-response curve for calculation of ED_{50} was generated.

Source: Homm et al. (87)

Regular use is essential to achieving high levels of use-effectiveness. Even a few omissions can lead to a large increase in failure rates: Malcolm Potts and Jack Grimshaw have estimated that 10 percent noncompliance would raise the Pearl index of failures by eight points (143).

What are the characteristics of contraceptive users—and especially of spermicide users—that seem to produce consistent use and high effectiveness? Four factors have traditionally been cited: (1) motivation, (2) education and affluence, (3) agreement between partners on contraceptive responsibility, and (4) experience in use of the method.

Motivation, or the strength of a couple's desire to avoid pregnancy, has some influence on whether any reversible contraceptive will be used effectively. US data comparing failure rates for all contraceptives among women who wanted no more births and among women who wanted only to delay the next birth showed a 50 percent lower failure rate among those who wanted no more births. Among women using various spermicidal preparations, 13.1 percent of those wanting no more births experienced failures within the first year of use compared with 16.7 percent of those wanting to delay births (199) (see Table 13).

In spite of efforts to control for motivation, there may be a bias in comparisons of the effectiveness of various methods because of self-selection. In other words, women who are most determined to avoid pregnancy will select the most effective methods and use them carefully, whereas women who are ambivalent or willing to take chances may select less effective methods and use them less rigorously, thus indirectly assuring that the methods they choose will continue to be regarded as less effective. This problem exists in all contraceptive evaluation since women cannot be randomly assigned to one or another method.

Past studies have also found that women with higher education and income are more likely to be successful users of barrier methods. US surveys in the late 1950s and early 1960s, before the pill and IUD became popular, found fewer contraceptive failures among the higher socioeconomic groups (26, 150, 203). This may still be true. The highly successful spermicide users in the study by Jack Squire and colleagues, for example, were generally in the higher social classes and well-educated (179).

A third characteristic that past studies have linked to successful contraceptive use is the quality of interaction between sex partners, usually summed up in the word "communication." Since spermicides must be used at the time of coitus, both partners have to be satisfied with the method and agree to pause in lovemaking in order to apply it. Reuben Hill and colleagues found that couples who discuss specific contraceptive methods and problems are more likely to be effective users than those who do not (83). Social class and communication between spouses are often interrelated. Lee Rainwater's US study of contraceptive performance among the urban poor showed that a lack of male cooperation and a female rejection of sexuality, more commonly found in poor couples, posed serious obstacles to effective use of barrier methods (150).

Experience in the use of spermicides also leads to more effective contraceptive performance. As decades of contraceptive effectiveness research have demonstrated, longer use provides lower failure rates (97). Long-term users adjust to the method and learn through trial and error (31). Conversely, the least successful users become

Table 13. Use-Effectiveness by Method in the USA and the United Kingdom, Failure Rates per 100 Women in First Year of Use (USA) and per 100 Woman-years (UK)

Method	USA Life-table failure rate in first year of use per 100 married women aged 15-44, 1970-1973			UK Pearl failure rate (per 100 woman-years) in cohort study of British married women aged 25-39
	Intention			
	Delay birth	Prevent birth	Standardized	
Pill	2.0	2.0	2.0	0.2[a]
IUD	5.6	2.9	4.2	1.9[b]
Condom	13.7	6.6	10.1	4.3
Diaphragm	15.9	10.3	13.1	2.4
Spermicides only	16.7	13.1	14.9	14.8[c]
Rhythm	28.8	9.5	19.1	NA

NA = not available
[a] Principally 50 μg estrogen in combined pill
[b] Lippes Loop C or D
[c] Based on 122 woman-years of use

Source: US—Vaughan et al. (199), UK—Vessey et al. (200)

pregnant early in the course of their experience with spermicides or drop the method.

Any effectiveness rate that assumes equal probability of failure in every month of exposure is subject to bias. If the period of observation is very short, the failure rate will appear misleadingly high; if the period is very long, the success of long-term users will be overrepresented. This is a major shortcoming of the Pearl Index, expressed as the number of pregnancies per 100 woman-years of use.* This distortion can be avoided by using life tables, in which failure rates are calculated for specific intervals after contraceptive use begins. Life tables can also be used to calculate extended use-effectiveness, a measure that emphasizes the importance of acceptability by counting as a method failure any unwanted pregnancy occurring after a certain method was first used, even if the method was deliberately dropped before the pregnancy occurred (199).

* A Pearl Index is calculated by multiplying the number of unwanted pregnancies by 12 (or 13, to approximate the number of 28-day menstrual cycles per year), dividing the product by the total number of months in which study participants were exposed to pregnancy, and then multiplying the result by 100.

The Role of the Provider

Early evaluations of spermicides and other coitally related methods may have overemphasized failures on the part of the user. Blaming the victim, as one observer points out, simply diverts attention from product or program deficiencies that could be remedied with additional effort (109). While some failures may be traced to lack of motivation, others may be caused by difficulty in securing supplies, inadequate instructions in contraceptive packages, or insufficient guidance and support from family planning personnel.

Patentex Oval/Encare: Problems in Evaluating Effectiveness

The case of Patentex Ovals illustrates the difficulty of evaluating spermicides accurately. The following information is available:

- Clinical data gathered by the manufacturer from nearly 300 West German physicians showed a failure rate of less than 1 per 100 woman-years, that is, a rate comparable to that of oral contraceptives (30). These physicians and the salesmen who recruited them were compensated at a higher rate for records reporting longer usage (46). Rates are not calculated on a life table basis; if long-term users are favored, low failure rates may not represent general experience with the product.
- Calculations based on the number of German women in Netherlands abortion clinics who became pregnant using Patentex Ovals and the estimated total number of Patentex users in Germany produced a failure rate of 4 to 5 per 100 woman-years (149).
- An authoritative US survey (199) and a major British cohort study (200) both yield failure rates of about 15 per 100 women or woman-years of spermicide use, as compared with 0.2 to 2.0 for oral contraceptives. The products used did not include Patentex Ovals, however.
- Sander-Cramer tests comparing the effectiveness of seven spermicidal products in vitro, fertilization tests in rabbits, and several other laboratory and human experiments do not indicate that Patentex Ovals performed in a manner superior to other spermicides tested (77, 86, 87, 117, 183).

There are no controlled studies of Patentex Oval users compared with users of Delfen, Emko, Neo Sampoon, or similar products. Although the manufacturer of Patentex Ovals claims the product has a unique combined melting and foaming action that not only immobilizes sperm but also completely blocks the cervical opening, this has not been demonstrated in comparisons with other products.

Because of these imperfect data, *The Medical Letter*, a nonprofit US publication on drugs and therapeutics, notes,

> Since the Encare Oval, unlike some other topical contraceptives, requires manual placement high in the vagina and a 10-minute waiting period for dispersion, *Medical Letter* consultants believe that the Oval will probably fail as least as often as other similar products (2).

A similar conclusion was reached by the authors of *Contraceptive Technology, 1978-1979*, who state:

> Concern has been raised over the effectiveness rates of the newly marketed Encare Oval, a vaginal suppository which melts, then foams to release nonoxynol-9. Effectiveness rates cited by the Oval manufacturer are derived from a very unconventional study design. Careful effectiveness studies are needed. Meanwhile, the authors believe the safest approach is to consider the Oval on a par with foam for effectiveness (81).

After a disagreement between the US manufacturer and the US Food and Drug Administration (USFDA) over the first published claims of high effectiveness, Encare advertisements and labeling in the US have dropped these claims and changed the claim that the product is effective up to two hours after insertion to one hour (46, 113). Advertisements now point out that Encare answers the concerns of women who worry about the pill, cannot use the IUD, and do not want the bother of a diaphragm. Encare is "so simple, it actually encourages the regular use necessary for effectiveness," according to the promotions.

One reason for the low failure rates—less than one pregnancy per 100 woman-years—in the clinical studies of Patentex Oval and Semicid suppositories cited in Table 14 is the individual attention given each user by participating physicians (85, 149). Jack Squire, Gary Berger, and Louis Keith of the United States report only one pregnancy attributable to method failure in a group of 326 Semicid suppository users averaging 14 months of use—a failure rate of 0.3 per 100 woman-years of use; in a subgroup of 107 previously pregnant women there were no failures. The subjects were all the patients of one doctor who instructed them individually, asked each of them to insert a suppository, and then performed a vaginal examination with a speculum to make sure that the suppository was properly placed (179). A study in the Federal Republic of Germany reported a failure rate of 0.3 per 100 woman-years for over 1,600 women using Patentex Ovals. In this study, 21 gynecologists—an average of one per 79 users—provided checkups at 3-month intervals (158).

By contrast, women using Patentex Ovals who apparently rely on printed instructions experience higher pregnancy rates. For example, one 3-month study at nine abortion clinics in the Netherlands in 1978, examining Oval use by 671 German women seeking abortions, found that average duration of use at time of contraceptive failure was nine months. Based on estimates of 400,000 users of Patentex Ovals in the Federal Republic of Germany and the proportion of Patentex Oval users among German women seeking abortions at the Netherlands clinics, Levie Querido and P. Schnabel suggest a failure rate of between four and five per 100 woman-years (149). Both US survey data and the large Oxford/Family Planning Association cohort study in Great Britain indicate relatively high failure rates for users of all spermicides—about 15 pregnancies per 100 women in the first year of use in the US survey and about 15 per 100 woman-years of use in the British study (199, 200) (see Table 13). These very much higher rates may reflect differences in method effectiveness. They also undoubtedly reflect differences in the motivation, education, and experience of users. At the same time, these differences probably also reflect the difference between the majority of spermicide users, who buy these products over the counter with no personal instructions or follow-up, and the small samples of women in clinical studies who receive extensive medical attention and support.

There are at least four specific ways in which spermicide providers, whether they are family planning programs, private physicians, clinics, or manufacturers, can encourage more effective use of spermicides: (1) by providing full and accurate instructions on insertion and use that will be comprehensible to any potential user; (2) by emphasizing the need for regular use with each act of intercourse; and, especially in clinic programs, (3) by inspiring confidence in the method if it is used regularly and consistently and (4) by providing short- and long-term follow-up.

Full and accurate instructions on how to use the spermicidal product should be included in every package. As pp. HH-98–99 show, many package inserts are neither simple nor clear. Even educated women might wonder, for example, where the "posterior fornix of the vagina" or the "vulval cervix" is located. Poorly educated women would have even greater difficulty following instructions that use these terms. The anatomical illustrations used are frequently confusing and seldom give sufficient guidance for an illiterate woman. In Bangladesh, Concerned Women for Family Planning is working with the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) to devise pictorial instructions that do not require a written text (see Figure 8, p. H-118).

A difficult point to convey in pictorial instructions is that the couple must wait 2 to 10 minutes for tablets or suppositories to melt before they have sexual relations (215). Observing this time interval is necessary for full effectiveness, but it is not emphasized in most instructions and it is particularly hard to illustrate where clocks are not in common use. Errors that can be made in spermicide use are listed in the box on this page.

Health personnel who provide person-to-person instructions must be able and willing to explain the female reproductive tract and how it works, since women who are ignorant about their genital organs will almost certainly not be effective spermicide users (24).

Above all, instructors and health personnel must emphasize the need to use spermicides regularly. Furthermore, they must make clear to the user that if these instructions are followed conscientiously, then spermicides can be reliable and effective. If users do not have confidence in the spermicide, they may not make the effort required to use it correctly. The provider is usually looked upon as an authority and can give users more confidence in the method. On the other hand, a provider who expresses doubt about a method may be contributing indirectly to less successful use and helping to create a self-fulfilling prophecy of failure.

Some Possible Errors in Spermicide Use

Packaging-related
- Failure to remove the wrapping from suppositories or tablets

Insertion-related
- Inserting the spermicide into the rectum instead of the vagina
- Not inserting the spermicide high into the vagina

Timing-related
- Having intercourse before the spermicide in suppositories or tablets is dispersed
- Having intercourse too long after insertion, when the product loses effectiveness

Omissions
- Not applying before subsequent acts of intercourse
- Not applying during supposedly infertile days of the menstrual cycle

Table 14. Effectiveness of Spermicidal Contraceptives, Selected Studies, 1975-1979

Author & Date	Ref. No.	Brand	Place	Number and Characteristics of Study Population	Nature of Use Instructions	Frequency of Follow-up	Woman-months of use	Number of Pregnancies	Failure Rate[a] (pregnancies per 100 woman-years)	
									Method	Method & User
Bonhomme 1976	27	Pharmelac cream/ jelly	France	51 "sexually active women"	Instructed to insert applicator before any relations; women having "normal conjugal life" advised to apply routinely before bed	NA	521	1	2.3	2.3
Bonhomme 1976	27	Pharmelac Ovule	France	455 "sexually active women"	Instructed to insert one suppository each day before going to bed "even when relations are not foreseen"; routine application encouraged by stressing antiseptic effect of product	NA	1,547	6	2.3	4.7
Brehm & Haase 1975[b]	30	Patentex Ovals	Federal Rep. of Germany	10,017 acceptors from clinics, general practice & Pro Familia centers, 41% "white collar workers," 32% "housewives," 12% "students"; 79% aged 15-35	NA	NA	63,759	43	0.5	0.8
Salomon & Haase 1977	158	Patentex Ovals	Federal Rep. of Germany	1,652 women, 85% with contraceptive experience, 34% "housewives," 20% "commercial occupation," 10% "students"; 80% aged 15-35	"Detailed briefing on application and working mechanism"	3-month intervals	34,506	9	0.2	0.3
Flavier et al. 1979	63	Neo Sampoon loop tablets	Metro Manila, Philippines	587 from 3 clinics with highest number of tablet acceptors; 3 months of use before study start; average age of both spouses: 31.5; well-educated (⅓ with college education)	NA	Monthly	NA	33	3.8[c]	7.9
Lopez et al. 1979[d]	114	Neo Sampoon loop tablets	Bogotá, Colombia	169 "normal fertile women in union, from low socio-economic strata" from 2 urban outpatient clinics, ≥ 2 live births, almost ½ with no previous contraceptive experience	Auxiliary nurse instruction on data recording, supplemented by instructional leaflet	1, 3, 6, and 12 months	NA	3[e]	NA	NA

Oblepias 1978	130	Neo Sampoon loop tablets	Philippines	60 selected for "intelligence, reliability, dependability"; mean age: 32.5; > 75% college graduates; mean parity: 3	Verbal instruction supplemented with printed instructions	Monthly	NA	4	NA	6.7[f]
Frankman et al. 1975	66	C-Film	Sweden	237 women attending 3 family planning clinics; no attempt was made to limit acceptors to highly motivated women; coital frequency at least once a week	Careful instruction on application to each patient; use by male recommended in early part of study but subsequently discontinued	NA	1,866	14	2	9
Grandjean et al. 1975	73	Pharmatex cream	Paris	245 private patients of 10 physicians; average age: 28.5; married average 6.8 years; 28% presented with exocervicitis, 54% with leucorrhea	Instructed to place cream in vagina "several minutes before relations"	Average 3-5 months	2,047	3	1.8	1.8
Rozenbaum 1977	157	Ta-ro-cap	France	732 private patients of 11 gynecologists, 7 general practitioners, 1 dermato-venereologist; "supposed to be fertile, of procreative age"; mean age 29 years, 61% less than 30 years; 61% of middle socioprofessional status or higher; mean coital frequency 10 per month	"Each doctor advised users systematically" on consistent, correct use	345 "regularly followed"	4,317	17	NA	4.7
Squire et al. 1979	179	Semicid	USA	326 generally "affluent, well-educated and highly motivated contraceptors," private practice patients; 11% using in conjunction with other methods	"Detailed personal instruction" from physician, with speculum examination to check proper placement	Acceptors told to return at regular intervals	NA	2	0.3[g]	NA
				Subgroup: 107 previously pregnant, using no other method			NA	0	0	0

NA = not available

[a] Figures are Pearl rates unless otherwise indicated.
[b] Results compiled from questionnaire distributed to 287 physicians in clinics, private practice, and Pro Familia centers. Manufacturer's sales personnel distributed questionnaire, and physicians were paid for completing form (2).
[c] Includes incorrect application of method
[d] Preliminary report of research in progress
[e] No pregnancies were reported at the 3-month follow-up; one each reported at 3½-, 4-, and 5-month follow-ups.
[f] Examination of records revealed unprotected coitus in all 4 cases. Form of rate calculation not given.
[g] Net cumulative rate at 24 months, calculated using life table method. Excludes months where adjunctive contraception used.

When spermicides are provided through clinics or health services, personal attention and follow-up are not necessary for medical reasons, but this additional attention does contribute to more effective use. In Gerald Bernstein's 1971 study of 2,932 Emko Foam acceptors, the majority of whom were indigent and not highly educated, special attention was given to instruction and each user was followed up at three-month intervals. Bernstein credited the resulting low failure rate of 3.98 pregnancies per 100 woman-years of use to these extra measures (22).

This situation illustrates a paradox in contraceptive use. On one hand, enhanced availability of spermicides, through community-based programs, commercial sales, and door-to-door distribution, clearly increases the acceptability and use of this method. On the other hand, to the extent that programs reach people who are less motivated, less experienced, and less exposed to the attention of sympathetic providers, these users will have higher failure rates. This is true for users of oral contraceptives as well (138). Conversely, if spermicides could only be secured on a prescription basis from clinicians who, like those cited above, are prepared to instruct patients individually, failure rates might all be in the range of 1 to 5 rather than about 15, but the number of users would be very much smaller.

Focusing on the needs of the user is more important than searching for a universally accurate failure rate. As Marianne Jackson, Gary Berger, and Louis Keith point out in their overview of the effectiveness of diaphragms, caps, and spermicides, it is misleading to cite "the" effectiveness of any method by itself. With spermicides, as with diaphragms, "any time a single rate is presented, it is a crude rate that is masking a tremendous variation in the expected failure rate for subsets of the population . . ." (97).

If generalizations must be made, an overview of earlier studies (of jellies, other products containing organometallic compounds, and the first of the surfactants) suggests that use-effectiveness rates for those products hovered around 20 failures per 100 woman-years (Pearl rate), of which physiological, or method, failures accounted for about half, or 10 failures per 100 woman-years, while user failures also amounted to 10 (97). An overview of more recent studies and surveys using products available during the 1970s suggests that the use-effectiveness of spermicides has improved, with about 15 failures per 100 woman-years (Pearl rate) (199, 200), of which method failures account for only about one-third or less—about 1 to 5 failures per 100 woman-years—while user failures now account for 10–14 failures per 100 woman-years. Depending upon the users and providers, these user failure rates can be reduced almost to zero.

Under these circumstances, it would be appropriate for health personnel and pharmacists to advise women or men who select spermicides that it is theoretically possible to achieve 95 percent protection or better by using proven spermicides regularly and correctly (97). But it would also be appropriate to warn potential users that in actual practice, failure rates are about three times as high, representing only 85 percent protection, because many users are not as careful as they need to be.

Because spermicides do have a special appeal for certain women—those who do not want to go to health centers, who are anxious about other methods, who are just beginning contraception, who have intercourse infrequently, or who need a temporary or back-up method—program administrators and health care providers should recognize the value of spermicides for these women, even if failures occur. The demographic impact of a situation where many women use imperfect methods without complete success may actually be greater than the impact of a program that provides a single, more effective method to a smaller number of acceptors. Moreover, those who wish to control their fertility should be able to make an informed choice among the different methods available.

The challenge to a family planning program in providing spermicides is to balance the benefits and shortcomings of the method with those of the available alternatives. In any program, funds, personnel, and time are always in short supply and must be utilized as efficiently as possible. Administrators must decide what resources to devote to promotion and supply of each family planning method in order to provide the best possible services. Of course, the introduction of any contraceptive method to new users requires additional instruction and effort. How much attention should be devoted to spermicides on a continuing basis will depend on the program resources available and the potential demand for spermicides in the population that the program serves. Unquestionably spermicide acceptability and effectiveness both can be improved where health care providers and other suppliers are willing to make the effort.

SAFETY

The safety of spermicides is one of their strongest assets. There are no reports of spermicide-related mortality nor of serious side effects. For this reason, little research has been devoted to the issue of spermicide safety as compared with the safety of systemic contraceptives, IUDs, and surgical procedures. Nonetheless, concern about the safety of all drugs is increasing. This means that, if and when new spermicides are introduced, the issue of safety will probably receive more attention.

Several considerations enter into the evaluation of spermicide safety:

- local reactions, such as tissue irritation, on the part of either partner
- systemic effects on the woman resulting from absorption through the vagina
- damage to a developing fetus from spermicide components or metabolites in the woman's circulation
- genetic damage to conceptions involving sperm damaged by spermicides.

With the exception of occasional local irritation, none of these potential problems has ever been reported. A

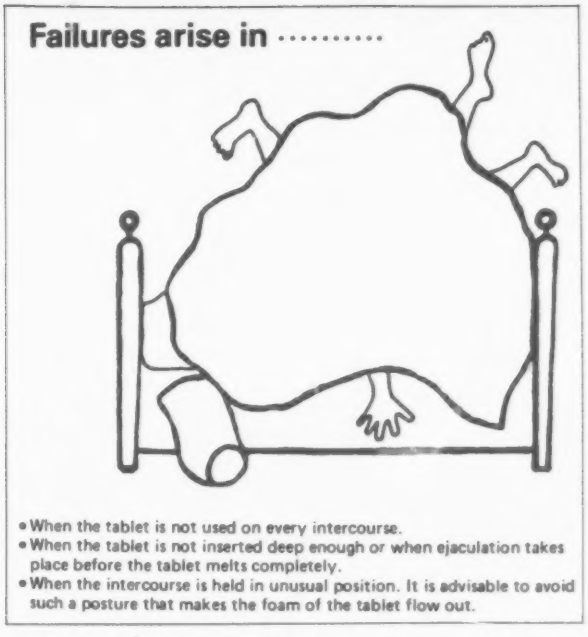


Figure 6. A Neo Sampoon brochure calls for careful use at every act of intercourse to assure maximum effectiveness. (Eisai Company)

woman using spermicides faces a greater risk of pregnancy, however, than a woman using sterilization, hormonal contraceptives, or an IUD. Since the health risks of pregnancy are usually greater than the risks of any form of contraception, this possibility is the only hazard to health that can be demonstrated after literally millions of woman-years of spermicide use.

Product Regulation

Vaginal contraceptive products have been commercially available in much of the world over a long period of time without rigorous testing for safety. In early 1972, however, the United States Food and Drug Administration (USFDA) began an ambitious program to review all drugs sold without prescription or medical supervision—about 300,000 different products. Such preparations are known as over-the-counter, or OTC, drugs to distinguish them from prescription pharmaceuticals. An extensive investigation of spermicide safety and effectiveness has been one part of this examination (113).

Chaired by Elizabeth B. Connell, the USFDA's Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products, one of 17 OTC advisory panels, reviewed information on 30 labeled ingredients (198) in approximately 50 products, evaluating specific commonly used ingredients rather than each individual product (45). In addition to laboratory and clinical tests, the histories of products on the market for many years—and particularly the number of complaints of side effects in relation to sales volume—were taken as indications of their safety (82).

Like other panels, the contraceptive review panel classified all products in three categories:
Category I. . . . OTC contraceptives and other vaginal products . . . generally recognized as safe and effective and . . . not misbranded.
Category II. . . . OTC contraceptives and other vaginal drug products not generally recognized as safe and effective or . . . misbranded.
Category III. . . . The available data are insufficient to permit final classification at this time (198).

The surfactants nonoxynol-9, octoxynol-9, and menfegol (Neo Sampoon's TS-88) were recognized as safe and effective. Evaluation of safety was based on animal tests reviewed by the panel and the history of use over the past twenty years. Evaluation of effectiveness was based on in vitro tests. The panel's review uncovered no reports of any long-term toxic effects, nor was any evidence found to indicate ill effects on the embryo from product components or metabolites in maternal circulation, although the panel noted that this issue has not been exhaustively investigated (198). The panel's classification of spermicides is shown in Table 15.

The panel classified compounds containing mercury as "effective" but "not generally recognized as safe" (Category II). (Although phenylmercuric acetate, or PMA, was the only compound containing mercury that was submitted to the panel for formal review, related compounds which also yield mercuric ions in solution were included in the panel's tentative findings because of similar toxic properties.) In fact, there have been no reports of harmful systemic effects to users of vaginal preparations containing PMA (or any other compound), and the panel found no data regarding the effects of PMA on human embryos.

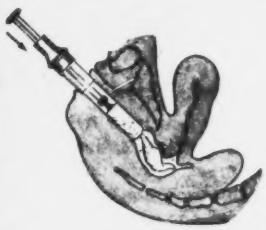
Table 15. Tentative Categorization of Selected Active Ingredients in Vaginal Contraceptives, with Considerations Cited, by the US Food and Drug Administration Advisory Review Panel on Over-the-Counter Contraceptives and Other Vaginal Drug Products, 1978

Active Ingredient	Category I: Recognition of safety, effectiveness, and no misbranding	Category II: No general recognition of safety and effectiveness, or misbranding	Category III: Insufficient data for final classification
Dodecaethylene glycol monolaurate			✓ Effectiveness
Laureth 10S			✓ Effectiveness
Menfegol	✓		
Methoxypolyoxyethyleneglycol 550 laurate			✓ Effectiveness
Nonoxynol-9	✓		
Octoxynol-9	✓		
Phenylmercuric acetate		✓ Safety	
Phenylmercuric nitrate		✓ Safety	

Source: US Food and Drug Administration (198)

BEST AVAILAB

Spermicide Instructions:



How accurately does this diagram depict the position of the vagina?

Does this drawing make clear what part of the anatomy it represents?

①性行為の２～５分前に入れてください。
②まず１錠を人さし指と中指ではさんで（図１）、膣の入り口に浅く入れます（図２）。つぎに人さし指で指の先に錠剤があるようにして、膣の奥に押し込み、**指のつけ根まで静かに入れます**（図３）。

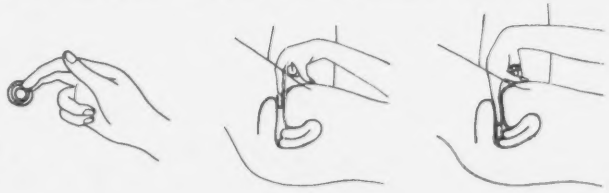


図 1　図 2　図 3

入れ方が浅いと溶けにくく、異物感がありますし、また避妊効果にも影響します。

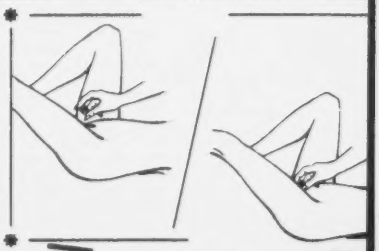
USE

by holding contraceptor barrel as shown. Insert deep into vagina.

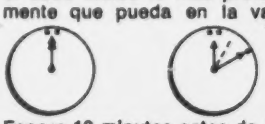
PUSH

container all the way into the barrel to deposit foam. Do not insert foam more than one hour in advance of intercourse.

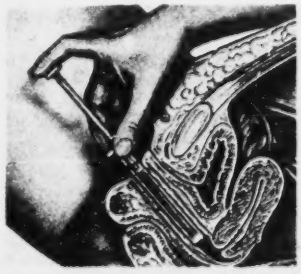
The text advises inserting the applicator or tablet deeply, but do the drawings make it clear?



1o. Introduzca el Ovulo **PROFAM** con el dedo índice lo más profundamente que pueda en la vagina



2o. Espere 10 minutos antes de la relación sexual, para que el óvulo se deshaga totalmente.No se haga ningún lavado vaginal durante las 8 horas siguientes a su aplicación



Testimonials:
In the scientific literature and at scientific meetings ANTIBION was repeatedly recommended as a reliable contraceptive, compare for instance the meeting of the German Gynecological Society, Zbl. Gyn. vol. 55, p. 1458; Arch. Gyn. vol. 144 p. 334; Zbl. Gyn. vol. 55, p. 3647.
ANTIBION has been tested and approved by the INTERNATIONAL PLANNED PARENTHOOD FEDERATION LONDON: Test protocols dd. 4th of December, 1961, 23 rd October, 1964 and 23 rd February, 1970.

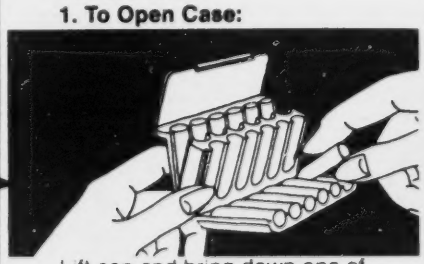
Contrary to the impression given, IPPF does not endorse products.

Will all women recognize this anatomical cross-section?

Some package inserts devote as much space to opening and closing the container as to using the product.

Directions:

1. To Open Case:



Lift cap and bring down one of the two banks of six chambers containing S'POSITIVE. To remove the S'POSITIVE, place your index finger at the bottom of the chamber and slide it out.

2. To Close Case:

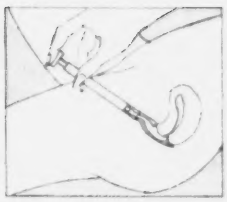
Return the bank of chambers to its upright position. Then close the cap to protect the remaining S'POSITIVES.

3.

LE COPY

Clear or Confusing?

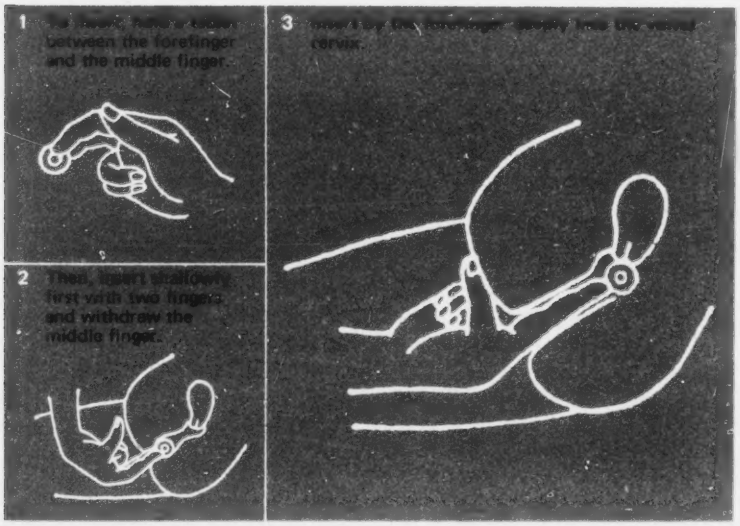
Does reluctance to picture a woman's external genitalia lead to illustrations too abstract to be clear?



(3) Insert the filled applicator well into the vagina and depress the plunger.
(4) Remove the applicator.

To clean applicator, pull plunger gently from barrel. Wash with soap and warm water. Hot water could damage the plastic.

How to use .....



Speton also offers, in addition, protection against infections by bacteria, fungi and trichomonads.

Fields of application:
Contraception.

Dose and direction for use:
On each occasion before sexual intercourse, a **Speton** tablet is inserted as high as possible (very important!) into the vagina. The tablet disintegrates in about 5 minutes.

The label fails specifically to advise waiting five minutes.

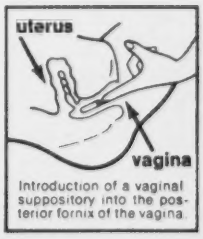
How many women know where the posterior fornix of the vagina is? The accompanying text contains a simpler explanation.

Semicid VAGINAL CONTRACEPTIVE SUPPOSITORIES

Safe... Effective... Easy to Use

DIRECTIONS FOR USE

Insert one suppository into the vagina fifteen minutes before intercourse. Use the forefinger to position suppository as deeply as possible into the vagina. Proper positioning is key to Semicid's efficacy. If intercourse is delayed more than one hour, or repeated, another suppository must be inserted. Semicid can be used safely as frequently as needed and directions should be followed each time. **SEMICID** provides a high degree of contraceptive protection. No method or product, however, can provide an absolute guarantee against becoming pregnant.



Introduction of a vaginal suppository into the posterior fornix of the vagina.

PRECAUTIONS: If douching is desired, always wait at least six hours after intercourse before douching. If you or your partner experience irritation, discontinue use. If irritation persists, consult your physician. Do not take orally.

If you have been told that it is dangerous for you to become pregnant, ask your doctor if you should use Semicid. If you miss your menstrual period, see a physician.

If tray mold container has been damaged, do not use.

KEEP OUT OF REACH OF CHILDREN

ACTIVE INGREDIENTS: Each suppository contains nonoxynol-9, 100 mg. Supplied in packages of 10.

WHITEHALL LABORATORIES INC., NEW YORK.

to Use:

ANT! To insure otection, it is ly necessary for you to ese instructions

Before intercourse—Using your finger, insert one S'POSITIVE suppository into the vagina, pushing it in until it will go no farther. Immediately the S'POSITIVE will start to dissolve blanketing the inner vaginal area Intercourse should be delayed 5 to 8 minutes to allow for full dispersion. S'POSITIVE remains effective 2 hours after insertion. If intercourse is repeated, another S'POSITIVE must be inserted.

The following considerations, however, led the panel to conclude that such compounds could be hazardous to the fetus or breast-feeding infant: (1) There is evidence that PMA is absorbed through the human vagina, and animal studies show vaginal absorption, systemic circulation, and distribution of PMA in various body tissues; (2) animal studies show that PMA and its metabolite, the inorganic mercuric ion, are distributed in various fetal tissues; (3) animal studies reveal that PMA can be toxic to embryos; (4) animal studies show that PMA is excreted in milk; and (5) mercury compounds are very reactive, poisoning membranes, blocking a wide range of enzymes, and in the case of PMA harming the cells of certain tissues, especially those of the nervous system (198).

If these findings are incorporated into the USFDA's final action, ingredients in Category III will be removed from sale unless the manufacturer shows that meaningful tests are underway. Manufacturers have two years in which to comply by setting up satisfactory testing procedures or removing the ingredient from commercial sale (82).

The USFDA Advisory Panel placed three active ingredients in Category III, or "insufficient data": dodecaethylene glycol monolaurate, laureth 10S, and methoxypolyoxyethyleneglycol 550 laurate. It also formulated safety research guidelines for these substances and for any vaginal contraceptives that may appear in the future. The guidelines require much more stringent testing for new products than for spermicides that have been marketed for a number of years.

Most other countries have no specific regulations on spermicides. One exception is the United Kingdom, where spermicides were added to the coverage of the Medicines Act in 1978. Under that law, which regulates labeling and advertising, claims of high reliability are now forbidden (4). Since 1968, to manufacture spermicides legally in the United Kingdom, producers must have approval from the Committee on Safety of Medicines (68). In Denmark, all barrier methods are covered by a 1975 ordinance requiring approval from the National Health Service before they may be sold (1). Since 1975, Finland has required National Board of Health approval for marketing of all barrier methods (3).

Side Effects

Local tissue irritation, the only known side effect of spermicides, has been reported by a few users in many clinical trials over the years. Recent concerns about more serious side effects, such as systemic or metabolic effects on the user or birth defects in users' offspring, arise from theoretical concerns and the growing knowledge that other, unrelated drugs can cause such effects.

One indication of the safety of spermicides comes from a long-term prospective study of more than 17,000 British women using oral contraceptives, IUDs, or diaphragms. The diaphragm users, a fourth of the total, who are presumably using spermicidal jellies with ingredients like those in spermicides used alone, experienced no higher incidence of disease or of hospital referrals than IUD or OC users except for hemorrhoids and urinary tract infections (200). Martin Vessey notes that an excess of cystitis and closely related conditions persists among the diaphragm users even after controlling for various other factors; this condition is often attributed to the pressure of the diaphragm on the urethra but warrants further evaluation.

Local irritation can occur because the mode of action of most popular spermicides is chemical. As surfactants, or detergents, they may be irritating to the vagina or the penis in the same way that some detergents are irritating to other parts of the body. Yet, with spermicides, the problem of local sensitivity seems to arise only very rarely. For example, the suspected adverse drug effects reporting system set up by the government Committee on Safety of Medicines in the United Kingdom received reports of only four cases of local irritation between 1970 and 1973 (143).

Clinical trials typically report some complaints of discomfort and a few discontinuations due to irritation, but rates vary widely even for the same product. Only 2.6 percent of Japanese users, for example, complained of irritation with Neo Sampoon tablets (96), compared with over 75 percent of Philippine women using the same product (130).

As knowledge of female reproductive physiology has increased, scientists have noted the capacity of the vagina to absorb a wide range of substances (46, 124, 198). This raises new questions regarding the possibility of systemic effects from vaginal contraceptives. Very preliminary studies by Milos Chvapil and colleagues on a small number of animals found that intraperitoneal and intravaginal doses of nonoxynol-9 in rats appeared to change their liver chemistry. Given in an aqueous solution to rabbits, a range of intravaginal doses calculated to correspond to 100 to 1,000 mg doses to humans was transferred rapidly to the blood stream (38), but the significance of this finding is not clear. H.F. Smyth and J.C. Calandra, in a 1969 study of nonoxynol and related substances fed to dogs and rats in varying doses for extended periods, reported that no histopathologic changes indicating toxic effects were seen (175). The Program for Applied Research on Fertility Regulation (PARFR) will be undertaking two studies of possible nonoxynol-9 effects on liver function, one in women who have used spermicides containing the surfactant over a long period and the other a prospective study of women using spermicides compared with users of other methods (212).

The question still remains whether the genetic message of a sperm could be damaged by a chemical contraceptive and whether such sperm could still unite with an ovum, resulting in fetal malformation (45). Current knowledge of the way in which spermicides attack sperm suggests that this is unlikely: spermicides rupture the sperm membrane, which, it is thought, should prevent the sperm from penetrating the ovum (6, 208). It would be possible to subject sperm to various concentrations of spermicides and then test their ability to penetrate the ovum in vitro, but this type of research has not yet been attempted (6).

Effectiveness as a Safety Issue

The effectiveness of contraceptive methods should be considered in any comparison of the safety of spermicides and other methods since pregnancy always poses some danger of maternal morbidity or death. This is particularly important in parts of the world where abortion is not readily or safely available to back up less effective contraceptive methods. Using figures derived from Christopher Tietze's computer model that calculates mortality associated with pregnancy and childbirth, legal abortion, and various contraceptive methods (186, 187, 188), Judith Bruce and S. Bruce Schearer added calculations for two levels of barrier method use-effectiveness. Their results show that pregnancy and childbirth to noncontraceptors poses by far the greatest risk; the safest alternative is either highly effective use of a barrier method (defined as a failure rate of 2.5 pregnancies per 100 users per year) or less effective use (defined as 21.5 pregnancies per 100 users per year) plus legal abortion for contraceptive failures (31). In developing countries where birth-associated maternal death rates are high, pills and IUDs may in practice be safer than spermicides because their use results in lower pregnancy rates.

Nevertheless, spermicides do have a place, particularly where abortion is available, but even in some circumstances where it is not. Bruce and Schearer have identified two groups of women in developing countries, for example, for whom barrier methods would be relatively safe alternatives despite the unavailability of legal abortion. The first group is women who are spacing births: since these women want more children, they are willing to accept the health risks associated with pregnancy, and even inconsistent use of a barrier method can delay subsequent births to some of them. The second group is women who do not have access to sterilization, IUDs, or pills or prefer not to use them; for these women, even a method of low effectiveness is preferable to no method at all (31).

The relationship between contraceptive effectiveness and safety underscores the need for effectiveness studies of spermicides in developing countries. Since there will always be many women who need short-term or immediate protection from pregnancy, even if it is not 100 percent effective, the need for spermicides will persist. The more effective these spermicides are, the greater their contribution will be to improved maternal health.

PROTECTION AGAINST INFECTION

In vitro tests suggest that spermicidal contraception may offer protection against both venereal disease and certain vaginal infections, but this therapeutic effect has not been fully confirmed in actual usage.

In vitro tests have shown that spermicides inhibit growth of *Neisseria gonorrhoeae* and *Treponema pallidum*, the organisms that cause gonorrhea and syphilis, respectively.

Table 16. Minimum Concentrations of Selected Spermicides Lethal to Venereal Disease Organisms

Brand	Minimum Lethal Concentration (%)*			
	Treponema pallidum	Neisseria gonorrhoeae	Trichomonas vaginalis	Herpes simplex II
Cooper Creme	10	1	1	10
Delfen Cream	10	10	1	10
Emko Foam	10	10	1	NA
Lorophyn Suppository	10	10	1	10
Lorophyn Jelly	10	10	1	10
Ortho Gynol Jelly	10	10	1	NA
Preceptin Gel	10	1	1	5
Neo Sampoon Loop Tablet	10	1	1	NA

NA = not available

* Dilutions in weight per unit volume, prepared in physiological saline solution

Source: Cutler & Singh (50)

Some commercial preparations were more potent than others against gonococci—specifically Preceptin Gel,* Cooper Creme,* and Neo Sampoon tablets—as shown in Table 16 (51). These differences may be caused not only by the spermicides but also by the wetting agents used in their bases (170).

In the only clinical study to date, regular users of Conceptrol Creme (Delfen Cream) had fewer cases of gonorrhea than nonusers. Among 132 women over 20 years of age who had had at least one gonorrhea infection in the preceding year and were at high risk of reinfection, in the first six months of study the women using Conceptrol had an infection rate that was only 3 percent of the control group rate (51). But this difference disappeared in the next six months (see Table 17). Many women may have stopped using the cream regularly either because they were less afraid of infection (51) or because they were all using other means to prevent pregnancy. The major obstacle to effective prophylaxis, John Cutler and colleagues concluded, was inconsistent use (51).

If spermicides do prevent venereal disease, their value in family planning and health programs would be enhanced. Venereal disease is widespread in both developed and developing countries. In 1972, the most recent year for which data are available, gonorrhea ranked among the three most frequently reported communicable diseases in ten industrialized countries (205). In the United States in 1977 and 1978, over one million cases of gonorrhea were reported in the nonmilitary population (197). In West Africa, gonorrhea is second in prevalence only to malaria among communicable diseases (132).

Gonorrhea can lead to infertility. Although epidemiological data are still meager, gonorrhea is thought to be a major cause of pelvic inflammatory disease (PID) in

* Product no longer available

Table 17. Rates of N. Gonorrhoeae Infection among Users of Conceptrol Cream and Unmedicated Controls

	First 6 Months		Second 6 Months	
	Treatment	Control	Treatment	Control
Number of women	37	50	17	27
Number of infections	1	11	4	6
Woman-months	144.4	205.1	69.3	120.2
Number of infections per 100 woman-months	0.69	5.22	5.78	4.99

Source: Cutler & Singh (50)

many parts of the developing world. PID, in turn, can produce sterility (17, 132). Nor is gonorrhea-related sterility unique to the developing world. According to one estimate, as many as 100,000 young women in the USA become sterile each year as a result of gonococcal infections (120).

Spermicides also protect against less serious but nonetheless troublesome vaginal infections. In one in vitro study all 21 vaginal contraceptive preparations tested inhibited growth of *Trichomonas vaginalis*, and six products, at least three of which contained phenylmercuric acetate, also halted the growth of *Candida albicans* organisms. These are two common causes of vaginitis (103).

Recent in vitro tests on herpes virus have produced similar results (11, 50, 141). This viricidal action may occur because surfactants such as nonoxynol-9 can break down the envelope that covers the herpes simplex virus, thus depriving it of the ability to infect (11). Even though clinical studies are lacking, anecdotal reports and observations suggest that many spermicides are effective against vaginal and possibly other reproductive tract infections (73, 157, 164, 165).

If more women realized that spermicides could protect against infection as well as against unwanted pregnancy, they might use the method more consistently and therefore more effectively. In a French study with Pharmatex suppositories, all 455 women were told about the therapeutic value of the product and instructed to use it every night whether they anticipated intercourse or not (27). Their pregnancy rate was 4.7 per 100 woman-years.

The effect of spermicides on venereal disease and other genital tract infections is a difficult field for research. A large study by Louis Keith, Gary Berger, and William Moss has found significantly lower rates of cervical gonorrhea in users of barrier methods as a group than in OC or IUD users (21, 100). The number of barrier method users, however, was too small to analyze condom, diaphragm, and foam users separately. Further research is needed to confirm these findings and to distinguish among the barrier methods.

A comparison between condoms and spermicides used alone would be particularly instructive since it would suggest the extent to which physical barriers and chemical barriers, respectively, reduce venereal disease. The research that would be easiest to design and would produce the clearest results would be unacceptable, however, since it would involve deliberately exposing users of various barrier methods and a nonusing control group to venereal disease. Cohort research like that of Cutler and colleagues encounters the problems of determining whether subjects have used the method consistently or of assuring that they do. Follow-up can also be difficult, since people with high rates of venereal disease reinfection may move frequently. Case-comparison, or retrospective, research like that of Keith and colleagues encounters the problem of determining the consistency of past use. Also, ideally, the sexual behavior of the case and comparison groups would need to be taken into account, which may be difficult to do. Still, attempts should be made to determine how effective spermicides and other barrier methods are in actual use as a prophylaxis against venereal disease and other infections. More knowledge in these areas would be extremely valuable not only to sexually active men and women but also to family planning and health program administrators.

RESEARCH AND DEVELOPMENT

Spermicide research and development currently center on improving base ingredients and devising better methods of application, for example, through vaginal rings or sponges. While better spermicidal agents are needed and there are some promising leads for research, little work has yet been done. For the developing countries, research is underway to make spermicides more durable in tropical climates and to identify spermicides that can be made from substances available in the household. Field studies financed by the US Agency for International Development to measure the acceptability of Neo Sampoon tablets are underway in 18 developing countries.

Public sector funding for research on vaginal contraception is very low, and private, commercial firms are primarily looking for simple variations on existing technology, which does not suggest any major improvements or new approaches. In fact, more stringent requirements by government agencies for safety testing may, unfortunately, discourage the introduction of new spermicides by commercial firms—especially firms that are satisfied with their present products—since entry into the US market may require as much as one million dollars to meet testing requirements (55). It is also possible that commercial firms that are satisfied with their present products and sales may use government regulations as an excuse to avoid research that would benefit the public at large but be expensive for the firms.

Product Research

Options for improving biological effectiveness of spermicides include changes in both the bases that deliver the spermicides and in the active ingredients themselves.

One goal of research on bases is to enable them to stay in place longer after application, thus assuring a longer period of effectiveness and allowing more time between application and coitus. Manufacturers conducting this research keep all results confidential since they may want to patent new products later. Reportedly, however, the longer-lasting bases now being tested with USFDA-approved spermicides are effective for 24 hours or more (147). Another experimental device utilizes agar gel as a base ingredient. Shaped like a diaphragm, it absorbs vaginal fluid and swells, releasing spermicides as well as blocking the cervix physically. Eventually—within one to eight hours—it liquefies (67).

Contraceptive film is being adapted for easier, more effective use by the male partner. Sometimes called a "water-soluble condom" or "spermicidal condom" (147), the device is more like a penile cap that does not cover the entire penile shaft. Two very fast-dissolving films have been chosen that allow rapid spermicidal action, but no in vivo testing has taken place yet (19). Earlier studies with a flat sheet of dissolving film, known as C-Film, yielded pregnancy rates ranging from 9 to 62 per 100 woman-years (66, 174).

Combining other barrier methods with spermicides to improve effectiveness deserves further exploration. Condoms lubricated with a spermicide proved highly effective for a group of British couples who had already been using condoms successfully (144). Controlled studies are needed, however, to evaluate the additional protection provided by spermicidal lubricants.

Other research centers on nondissolving delivery systems, such as the World Health Organization's spermicide-releasing vaginal rings. These devices would allow continuous protection over long periods of time with easy discontinuation by simply removing the device. Pilot clinical trials are underway in Japan, Mexico, and the United Kingdom on vaginal rings medicated with nonoxynol-9. The studies will determine ability to immobilize sperm in cervical mucus, degree of local irritation, and levels of nonoxynol-9 in cervical mucus and plasma (206). By the end of 1978 WHO funding for the project had amounted to $77,500 (US) (181). In the USA, the Proctor and Gamble Company is conducting research on rings and U-shaped controlled-release spermicidal devices (59).

The intravaginal sponge, an ancient contraceptive technique, is now being investigated as a new spermicide delivery system. Recent interest in sponges was stimulated by Milos Chvapil at the University of Arizona. In 1975, Chvapil began to study the natural protein, collagen, as a mechanical barrier method which could absorb semen rapidly, thus preventing sperm from reaching the ovum (201). Because the efficacy of the sponge alone may be low, however, it is being adapted to contain spermicide; it is thus intended to act primarily to keep spermicides in place against the cervix (38).

Polyurethane sponges whose primary action is also spermicide delivery are being developed and tested as well (185, 195). One polyurethane spermicidal sponge, the Collatex sponge, has been tested in seven countries by the International Fertility Research Program. In Yugoslavia, where 100 women have been followed for more than six months, the pregnancy rate was 1.1 per 100 women, with a continuation rate of 85.6 percent. In Egypt, Bangladesh, Colombia, and Mexico, however, only about one-half of the 179 original participants returned for follow-up; of these, nearly one-half (43 of 97) discontinued using the sponge. Discomfort during intercourse was the reason most often given. In Colombia the study was terminated because 6 of the 58 users became pregnant in 78 woman-months of use; the Bangladesh study ended because of low acceptance (72).

In contrast to the interest in new bases and delivery systems, there appears to be little research interest in developing new spermicidal agents, despite the need for them. Ideally, spermicidal action should be instantaneous (167) and effective even in very dilute solutions (169). The most potent spermicide now available is not effective

New Publications

During 1979 and 1980 the following publications on barrier methods of contraception are expected to be available:

New Developments in Vaginal Contraception, proceedings of the International Workshop on New Developments in Vaginal Contraception, held in Guatemala City, Guatemala, in April 1979. The eighth volume in the Program for Applied Research on Fertility Regulation (PARFR) Series on Fertility Regulation, the book is edited by Gerald I. Zatuchni, Aquiles Sobrero, J. Joseph Speidel, and John J. Sciarra and published by Harper and Row, Hagerstown, Maryland 21740, USA.

IPPF Handbook of Contraceptive Technology, a revised and updated version of the International Planned Parenthood Federation's comprehensive guide to family planning methods, including barrier methods. The *Handbook* can be obtained from the IPPF, 18-20 Lower Regent Street, London SW1Y 4PW, UK.

Vaginal Contraceptives, a book by Marianne Jackson, Gary S. Berger, and Louis Keith, assesses knowledge of the effectiveness of spermicides and diaphragms. The publisher is G.K. Hall and Company, 70 Lincoln Street, Boston, Massachusetts 02111, USA.

Information Services Bulletin, September 1979 issue, offers a bibliography of selected educational materials on barrier methods for users and instructors. The *Bulletin* can be obtained from the National Clearinghouse for Family Planning Information, P.O. Box 2225, Rockville, Maryland 20852, USA.

in in vitro tests beyond a dilution of 1 percent or so (77). Furthermore, a wider range of active ingredients would be useful, allowing people to try alternative preparations if they prefer spermicides but find one product or another irritating.

One promising area for research is the biochemistry of sperm. Sperm have enzyme systems that provide motility and enable them to penetrate the ovum for fertilization. The sperm acrosome, a saclike structure covering the anterior portion of the sperm head (207), contains the enzymes that enable the sperm to pass through the outer layers of the ovum. One of these enzymes, acrosin, can be inhibited by such synthetic substances as p-nitrophenyl-p′-guanidino benzoate (NPGB), which prevents conception when applied vaginally in animals (211). The main advantage of such enzyme inhibitors is that they work on a different principle from spermicides; instead of immobilizing the sperm, they prevent fusion of the sperm with the ovum. Thus, a mixture of spermicides and enzyme inhibitors may be more effective than spermicides alone. Moreover, it may be possible to develop enzyme inhibitors that are specific for spermatozoa, thus greatly lowering any chance of side effects (209).

Several other theoretical possibilities have yet to be explored. The coagulation of semen immediately after ejaculation, followed by liquefaction, is a biological mechanism with potential significance for contraception. The coagulum apparently protects the sperm inside it from vaginal acidity (125). It also shields sperm from spermicidal agents. To make spermicides more effective, it would be useful to find substances that penetrate the semen gel before it disperses, particularly if the coagulum makes direct contact with the cervix (169). An alternative would be to accomplish the reverse: to identify agents that prevent liquefaction of the semen after it has coagulated. This would trap the large number of sperm in the coagulum and prevent their passage into the cervix.

Still another opportunity for vaginal contraceptive development lies in altering cervical mucus to prevent or markedly delay sperm penetration. Although theoretically promising, such agents have yet to be developed (211). Another strategy for increasing effectiveness would be to combine active ingredients having different modes of action; for example, a spermicide could be added to a substance that alters cervical mucus plus an ingredient that prevents sperm from penetrating the ovum (208).

Substances such as iron (110, 111) and selected saponins (182) have displayed spermicidal activity and did not prove irritating in initial testing, but their development as spermicides requires further investigation.

Spermicide research for developing countries includes adapting substances to local conditions. The International Committee for Contraceptive Research has modified the Encare with tropical heat conditions in mind, to prevent melting before use. The formulation is currently undergoing studies for vaginal irritation (128).

Other research seeks to capitalize on the basic advantages of simplicity and accessibility by developing spermicides made out of household substances that can be used if no alternatives are available. This research is largely an individual effort of US researchers (5, 162, 192). In vitro testing of 50 ingredients commonly found in kitchens has narrowed the possibilities to four substances, the best proportions and consistency of which are now being determined (5).

Homemade Spermicides

The 1974 Family Planning Handbook for Doctors *offers information on household substances that can be used as spermicides by applying them to pads, plugs, or sponges when no other methods are available. (Postcoital douching with these or other solutions is ineffective, the handbook notes.)*

Remarks. [Cloth pads, plugs of cotton or silk manufacturing waste, or sponges] used with one of the spermicidal solutions mentioned below and placed high in the vagina to cover the cervix offer better protection than no method at all. They can be made more effective by being used in conjunction with one of the manufactured spermicides, i.e. creams, pastes, jellies or foam.

Spermicides

1. Vinegar and water or lemon juice and water. One part of the acid vinegar or lemon juice mixed with 20 parts of warm boiled water is an effective spermicide.

2. Oils. Any clean, sweet or cooking oil (except mustard) or fat, including butter and margarine, is suitable for smearing over the plug or sponge.

3. Soap solution. This can be prepared by dissolving a 1–1½ cm (¼–½ inch) cube of plain pure soap in a litre or quart of warm boiled water.

Strong soap (e.g. carbolic) or soap powders and detergents of all kinds must be avoided because of their injurious effect on the lining of the vagina.

Source: IPPF *Family Planning Handbook for Doctors*, 1974 (104)

Homemade spermicides were suggested in the most recent (1974) IPPF *Family Planning Handbook for Doctors* (see box, above) (104). Malcolm Potts, advocating simple, immediately available preparations like these, points out that a highly sophisticated technological approach to improving barrier methods of contraception is counter to their basic advantage of simplicity and may ignore the needs of many couples in developing countries. In India, for example, a spermicide of cottonseed and mustard oil provides "a peasant solution to a peasant problem" (142).

Research in Use and Acceptability

The acceptability of any contraceptive method is as important as its physiological effectiveness, particularly in the case of spermicides, where use must be consistent. The US Agency for International Development (USAID) is providing 15 million Neo Sampoon foaming tablets for pilot acceptability studies in 18 countries (169) and plans

to substantially increase procurement and distribution of the tablets (168). Half of the tablets are for the first time being individually packaged, an innovation that should allow more variety in distribution techniques (169).

Most of the USAID pilot projects involve house-to-house distribution. In Egypt, for example, where the program covers the entire Menouffia Governate, workers provide pills, condoms, and referrals for IUD insertion and sterilization as well, but offer the tablets to lactating mothers and those frequently separated from their spouses (168). In early 1978 the International Fertility Research Program (IFRP) began field studies on the acceptability and effectiveness of Neo Sampoon tablets in 4 of the 18 countries —Bangladesh, Colombia, Egypt, and Mexico. In this study physicians at public hospital clinics and in private practice gather information on 150 acceptors in each country. Participants receive tablets free of charge. Very preliminary data from all four countries show a failure rate of about six after approximately 1,000 woman-months of exposure (168). More women in Bangladesh—32 percent —complained of heat from the tablets than in any of the three other countries (118).

Research Support

Funds for barrier method research account for only a small portion of total public sector expenditures for contraceptive research. Judith Bruce and S. Bruce Schearer of the Population Council, using data reported to the World Health Organization, estimated that in 1976, of a total of $30.2 million spent by 14 public agencies on applied contraceptive research, only $50,000 went to barrier method research; in 1977, of a total of $33.7 million, $140,000 was spent on barrier method research (31). Gerald Zatuchni of the Program for Applied Research on Fertility Regulation has estimated that, if private industry is included, expenditures for research on barrier methods might total roughly one million dollars (212). (Estimates are, of course, only rough approximations, since the dividing line between applied and basic research is sometimes arbitrary, and different subcategories of behavioral research, such as marketing studies, may be omitted by some institutions.) US government funding of research on barrier methods through the National Institute of Child Health and Human Development (NICHD) is projected at about $450,000 for Fiscal Year 1979, a figure that amounts to less than 10 percent of NICHD funds for contraceptive research (25). Even at this modest level there may not be enough high quality research proposed to merit funding (26).

Although it is not possible to state the exact extent and goals of corporate research, it appears that such efforts are not geared to producing fundamentally new technologies (31, 45). As one observer pointed out, private research and development in the United States will probably respond to the dual trends of increased consumer demand and increased product regulation largely with new products that contain already approved spermicides in commonly used bases, thus avoiding the extensive and expensive safety reviews now required for any new components (55).

Given the valuable role that spermicides can play in family planning and their present weaknesses, priority should be given to the following research and development objectives:

Product-related Improvements in Effectiveness

- spermicides that are potent even in weak concentrations (31, 169)
- bases that disperse faster in order to provide maximum chemical availability of active ingredients (31)
- bases that last longer (31, 164)
- bases that provide more adequate coverage of the cervical os (31)
- finished products that do not spoil in tropical heat and humidity, including vaginal suppositories that will remain intact until used (31, 167)
- a broader range of spermicidal agents, including ones that can affect biological mechanisms such as cervical mucus permeability or semen coagulation (204, 208)
- comparative field studies on spermicide effectiveness, including comparisons with other methods (24, 31, 43)
- combinations of methods such as spermicide-lubricated condoms.

Provider-related Improvements in Effectiveness

- improvements in the illustrations and text of printed instructions to make them complete, accurate, and easy to understand and follow (31, 164)
- evaluation of the comparative effectiveness and efficiency of printed versus face-to-face instruction
- attention to the attitudes, knowledge, and training of those who provide services, in order to eliminate biases and insure the most effective guidance and follow-up (24, 195).

Research in Health-related Issues

- safety studies related to the issue of penile and vaginal absorption of chemicals (31, 43)
- studies to identify and compare compounds that combine contraceptive action with protection against venereal disease and/or treatment of vaginitis (31, 50, 164)
- studies to compare spermicide and condoms as prophylactics against venereal diseases.

Figure 7. The acceptability of spermicides like these, specially packaged and distributed in community-based and social marketing programs, is now under study around the world.

Research and Improvements in Acceptability

- methods of application that can be used very simply in conditions of little privacy, with easy disposal of waste materials (31, 163, 204)
- improvements in containers, especially in inserters for tubed products and aerosols, for easier application (31)
- improvements in products and means of application that would enhance rather than interrupt sexual activity
- pilot tests including potential users to determine what factors influence acceptability among couples in different cultures (31, 163).

User Studies

- expanded research on beginning users of barrier methods, particularly adolescents, together with research on the health effects on adolescents of different types of contraceptive methods (31)
- studies comparing acceptance, continuation, and failure rates of users introduced to spermicides through commercial, clinic, and medical sources to identify programmatic and individual characteristics for successful use.

As many in the family planning field are beginning to recognize, it is not enough merely to criticize imperfect products or to blame careless users (24, 31, 109). A more constructive approach is to analyze systematically the problems associated with each method and to look with both knowledge and imagination for ways to overcome them. If the chemical composition of spermicides is improved through further scientific research, if packaging is modified to meet consumer needs, and if product distributors provide easier access and better guidance for potential users, spermicides can undoubtedly play a larger and more useful role in meeting the world's need for a broad range of safe, effective, and acceptable family planning methods.

TABLES

Table 1. Characteristics of Selected Spermicidal Contraceptives, by Product Type and Brand Name

Brand (Manufacturer, Country)	Size/ Weight	Active Ingredient(s)	Inert Ingredient(s)	Shelf Life	Price
FOAMING TABLETS					
Antibion (Patentex GmbH, FRG)		Nonoxynol-9, 0.024 g	Aluminum acetotartrate		
CCC (Yamanouchi Pharmaceutical Co. Ltd., Japan)	1.5 cm diameter /850 mg	Polyoxyethylene-nonyl phenyl ether, 50 mg	Potassium hydrate tartrate, 385 mg; sodium bicarbonate, 170 mg; light anhydrous silicic acid, 50 mg; hydroxypropyl starch, 103.5 mg; crystalline cellulose, 34.5 mg; synthetic aluminum silicate, 34.5 mg; hydroxy propyl cellulose, 5.5 mg; talc, 17.0 mg		
Neo Sampoon (Eisai Co., Japan)	1.5 cm diameter	p-Methanylphenyl polyoxyethylene (8.8) ether (TS-88), 60 mg	Dioctyldisodium sulfosuccinate, 5 mg; benzethonium chloride, 4 mg; starch, 111 mg; potassium bitartrate, 326 mg; sodium bicarbonate, 160 mg; silica anhydride, 30 mg; microcrystalline cellulose, 33 mg; polyvinylpyrolidone, 21 mg	At least 3 years	$1.20 (US) per dozen
Semori (Luitpold-Werk, FRG)		8-Hydroxyquinoline sulfate, 0.5%			
Speton (Temmler-Werke, FRG)	1.3 cm diameter	Disodium-4-(N-chlorsulfamoyl)-benzoate, 0.0095 g		4 years	Retail: $0.80-4.40 (US) per dozen[a]
SUPPOSITORIES & OTHER INSERTS					
A-gen 53/Syn-a-gen (Dr. Herbrand KG., FRG)		Trisodium salt of sulfuric acid ester of a polysaccharide, 0.1%[b]			
Agena (Lusofarmaco S.A., Italy)	2.5 cm × 1.3 cm /3.2 g	Nonoxynol-9, 0.250%; dodecaethylene glycol monolaurate, 0.025% benzethonium chloride, 0.125%	Polyethylene glycol, 2.675%; purified water		Retail: approx. $1.60 (US) per pack of 12

Table 1 (Continued)

Brand (Manufacturer, Country)	Size/ Weight	Active Ingredient(s)	Inert Ingredient(s)	Shelf Life	Price
Contraceptivum E (Koronis/Mapa, FRG)[c]		p-n-Nonylphenoxypolyethylene glycol, 0.024 g; sodium dioctylsulfosuccinate, 0.036 g	Lactic acid		
Encare/Patentex Oval (foaming) (Eaton-Merz Laboratories, USA)	2.8 cm × 1.4 cm/3.3 g	Nonoxynol-9, 2.27%, 0.075 g	Carbowax, sodium bicarbonate, tartaric acid	2 years; expiration date on box	Retail: (Encare) $4.25 (US) per dozen; wholesale: $2.37 (US) per dozen
Lady Suppositories (Koronis/Mapa, FRG)[c]		p-n-Nonylphenoxypolyethylene glycol, 0.024 g			
Lorophyn (Norwich International)[d]	2 g	Phenylmercuric acetate, 0.4 mg	Methylbenzethonium chloride, 0.4 g; methylparaben, 0.2 mg; in a water miscible base	At least 3 years	Retail per pack of 12: Mexico, $1.00 (US); Colombia, $1.05 (US); Peru, $.48 (US)
Norforms (Norwich International)[d]	2 g	Phenylmercuric acetate, 0.4 mg; polyethylene glycol "1000," 1.6 g	Methylbenzethonium chloride, 0.4 mg; methylparaben, 0.2 mg; sorbitan sesquioleate 0.10 g; polyoxyethylene palmitate, 0.2936 g	At least 3 years	Retail per pack of 12: Mexico, $1.00 (US); Colombia, $1.03 (US)
Orthoforms (Ortho Pharmaceutical Ltd., UK)	1.6-1.77 g	Nonoxynol-9, 5%	Polyethylene glycol		Retail: $4.00 (US) for pack of 15
Profam (Norwich Pharmacal Co. de Mexico)[e]	2.7 cm × 2.3 cm /2.268 g	Nonoxynol-9, 168 mg			
Rendells (W.J. Rendell Ltd., UK)	1.8 cm × 2 cm	Nonylphenolethylene oxide, 0.08 g	Fractionated palm kernel oil, 1.52 g	At least 7 years	
Semicid (Whitehall, USA)	2.7 cm × 0.8 cm/ 1.4 g	Nonoxynol-9, 6.6%	Carbowax (polyethylene glycols)	2 years	$3-4 (US) per dispenser of 10
Si-O-Safety Ovals (Petri GmbH KG., FRG)	2.4 cm × 1.5 cm	Quinine-hydrochloride, 0.0625 g	Boric acid, 0.0625 g		
S'positive (Jordan-Simner, USA)	2.6 cm × 0.8 cm /1.4 g	Nonoxynol-9, 5.8%	Citric acid, sodium carbonate, sodium lauryl sulfate, fragrance, excipient A5[f], excipient D[f], benzethonium chloride	2 years; expiration date on box	Suggested retail: $3.75 (US) per dozen
Staycept (Syntex Pharmaceuticals Ltd., UK)		Nonoxynol-9, 0.096 g	Methylparaben, 10.0 mg alcohol, dioctyl sodium sulphosuccinate, purified water	5 years	Retail: $1.27 (US) per 10
Ta-ro-cap (Laboratoires Human-Pharm, S.A., France)	18 mm diameter/ 0.25 g	Phenylmercuric nitrate, 2.05 mg; benzethonium chloride, 4.55 mg	Methylparaben, 10.0 mg	3 years	

Table 1 (Continued)

Brand (Manufacturer, Country)	Size/ Weight	Active Ingredient(s)	Inert Ingredient(s)	Shelf Life	Price
SOLUBLE FILM					
C-Film (Potter & Clark Ltd., UK)	5 cm^2/ 150 mg	Nonoxynol-9, 28%	Water soluble film of dried polyvinyl alcohol	5 years	
JELLIES					
Agena (Lusofarmaco S.A., Italy)		Nonoxynol-9, 5%; dodecaethylene glycol monolaurate, 5%; benzethonium chloride, 0.25%	Sodium carboxymethylcellulose, 1.8%; purified water		Retail: approx. $1.60 (US)
Confidol (Pharmasal, FRG)		Dihydrocuprein, 0.1%	Boric acid, 3%; lactic acid, 1%; tartaric acid, 0.2%; aluminum lactate, 5%; calcium lactate, 1%; glycerin, 15%; gum tragacanth, 5%		
Flavo-cept (cherry) (Nova Corp. of America, USA)		Polyethylene glycol 600 monolaurate			
Gelifax (Laboratoires Labaz, France)		Nonoxynol-9, 1%	Sodium lauryl sulfate, 1.05%; sorbic acid, 0.25%		
Koromex-2A (Holland-Rantos Co. Inc., USA)		Nonoxynol-9, 2%	Purified water, propylene glycol, boric acid, sorbitol, cellulose gum, soluble starch, simethicone	5 years	Retail: $3.05 (US), 135 g tube; $3.40 (US) 135 g tube with applicator; institutional: $8.40 (US) per dozen, 135 g tubes; $12.00 (US) per dozen, 135 g with applicator
Patentex (Patentex GmbH, FRG)		Nonoxynol-9, 1%	Aluminum acetotartrate, 1.5%		
Ramses Vaginal Contraceptive Jelly (Schmid Laboratories, USA)		Nonoxynol-9, 5%	Boric acid, 1%; ethyl alcohol, 5%		Retail: $4.38 (US) 3 oz tube with applicator; $4.38 (US), 5 oz tube; $3.60 (US), 3 oz tube
Staycept (Syntex Pharmaceuticals Ltd., UK)		Octoxynol, 1.0%	Acacia, perfume CN/A127, castor oil soap, 30%; propyl hydroxybenzoate, gum tragacanth, potassium hydroxide, boric acid, glacial acetic acid, glycerol, purified water	5 years	Retail: $1.48 (US) per 80 g tube
CREAMS/PASTES					
Conceptrol (Ortho Pharmaceutical Corp., USA)		Nonoxynol-9, 5%		3 years	Retail: $1.93 (US) per 6; $2.74 (US) per 10; institutional: $1.30 (US) per 6; $1.92 (US) per 10

Table 1 (Continued)

Brand (Manufacturer, Country)	Size/ Weight	Active Ingredient(s)	Inert Ingredient(s)	Shelf Life	Price
Delfen (Ortho, USA)		Nonoxynol-9, 5%		3 years	Retail: $3.35 (US) 70 g tube with applicator; $2.85 (US) 70 g tube only; institutional: $1.24 (US) 70 g tube with applicator; $.77 (US) 70 g tube only
Flavo-cept (raspberry) (Nova Corp. of America, USA)		Nonoxynol-9	Citric acid	3 years	$4.00 (US) per tube; wholesale $28.80 (US) per dozen
Profam (Lemery, S.A., Mexico)[e]		Nonoxynol-9, 12.5%		5 years	
PRESSURIZED FOAMS					
Delfen Foam (Ortho Pharmaceutical Corp., USA)		Nonoxynol-9, 12.5%		3 years	Retail: $2.96 (US) 20 g vial with applicator; $2.73 (US) 20 g vial; $3.64 (US) 50 g vial; institutional: $1.13 (US) 20 g vial with applicator; $.71 (US) 20 g vial; $1.09 (US) 50 g vial
Emko Foam/Emko Pre-Fil Foam/Because Contraceptor (Schering Corp., USA)		Nonoxynol-9, 8%	Benzethonium chloride, 0.2%	3 years	Institutional: $1.04 (US) 90 g can
Koromex (Holland-Rantos Co. Inc., USA)		Nonoxynol-9, 12.5%	Water, propylene glycol, propellant 114, isopropyl alcohol, Laureth-4, cetyl alcohol, propellant 12, PEG-50 stearate	5 years	Retail: $2.40 (US) 22 g vial with applicator; institutional: $13.00 (US) per dozen, 22 g vial with applicator (3 dozen/ shipping case only)
Patentex (Patentex GmbH, FRG)		Nonoxynol-9, 8%			
Profam (Lemery, S.A., Mexico)[e]		Nonoxynol-9, 12.5%			

Note: Prices of non-US products expressed in US currency are based on exchange rates of July 24, 1979.
[a] Speton—Price range for all markets worldwide
[b] Syn-a-gen (Mexico)—Also contains nonoxynol-9, 230 mg
[c] Contraceptivum E, Lady Suppositories—Source: Hoffman & Tauber (85)
[d] Lorophyn not sold in the United States, Norforms without spermicide are sold in the United States as a feminine deodorant only. Lorophyn and Norforms containing spermicide are sold throughout Central America, Argentina, Brazil, Colombia, Mexico, Peru, and Venezuela.
[e] Profam—Manufactured for Profamilia, S.A., Mexico.
[f] S'positive—Natural vegetable oils composed of a combination of mono-, di-, and triglycerides.

Table 2. Deliveries of Spermicidal Contraceptives Financed by the United States Agency for International Development, by Recipient Country, 1975-1978[a]

Country	Pressurized Foam (in 90 g containers)				Foaming Tablets (in 20-tablet containers)	Jelly/Cream (in 135 g tubes)			
	1975	1976	1977	1978	1978	1975	1976	1977	1978
AFRICA									
Benin	1,548	540	—	1,008	—	1,008	—	504	—
Botswana	96	—	—	324	—	—	—	252	181
Ethiopia	—	—	—	504	—	—	—	108	—
Egypt	—	—	216	—	25,000	612	—	550	1,008
The Gambia	504	1,008	—	—	—	—	—	—	—
Ghana	123,240	41,004	40,968	—	25,056	504	1,008	—	—
Kenya	—	—	—	1,008	—	864	1,008	—	720
Lesotho	144	1,008	—	—	—	—	1,008	—	—
Liberia	—	1,008	—	—	—	—	—	—	—
Mauritius	216	—	—	—	—	216	—	—	—
Morocco	—	—	—	—	—	—	—	—	1,008
Nigeria	1,440	1,500	—	—	—	1,008	—	—	—
Seychelles	216	300	—	—	—	216	360	—	—
Sierra Leone	2,016	—	—	—	—	2,016	—	—	—
Tanzania	—	1,200	—	6,012	—	1,224	576	2,016	2,016
Togo	—	—	—	720	—	—	—	—	468
Tunisia	2,016	—	—	—	5,000	—	—	—	—
Uganda	—	—	—	1,224	—	—	—	—	—
Zambia	—	—	—	—	—	504	—	—	—
Subtotal	131,436	47,568	40,968	10,800	55,056	8,172	3,960	3,430	5,401
ASIA & PACIFIC									
Afghanistan	—	—	15,012	—	—	25,000	10,008	20,000	—
Bangladesh	7,200	3,024	104,004	5,004	—	2,412	1,008	—	5,009
Cambodia	504	—	—	—	—	—	—	—	—
Cyprus	—	36	—	—	—	—	1,440	—	—
Iran	504	504	—	—	—	5,004	—	2,016	—
Iraq	1,008	—	—	—	—	—	7,056	—	—
Israel	—	504	—	1,008	—	—	—	—	—
Korea	—	—	—	—	20,000	—	—	—	—
Laos	—	—	—	—	—	1,008	—	—	—
Lebanon	96	—	—	504	—	216	504	—	—
Malaysia	144	144	—	—	—	756	—	108	—
Nepal	5,016	—	—	2,016	—	5,004	—	—	1,512
New Guinea	72	—	—	—	—	—	—	—	—
Pakistan	5,016	10,008	—	—	—	3,000	—	—	—
Sri Lanka	—	—	—	252	5,000	—	504	—	—
Syria	—	504	—	—	—	—	5,040	—	—
Thailand	—	—	—	—	25,040	144	—	—	—
Subtotal	19,560	14,724	119,016	8,784	100,040	42,544	25,560	22,124	6,516
LATIN AMERICA									
Argentina	—	—	—	—	—	—	—	—	2,016
Bolivia	1,008	1,692	—	—	—	—	864	—	—
Chile	5,016	—	—	9,036	—	5,004	—	—	5,004
Colombia	29,208	20,016	—	—	—	—	—	—	—
Costa Rica	5,016	5,256	—	—	—	10,008	12,024	—	35,064
Dominican Rep.	6,000	8,028	—	—	—	—	—	—	—
Ecuador	22,032	9,000	2,016	—	8,000	2,016	—	504	2,808
El Salvador	5,988	1,200	—	—	—	6,012	—	—	—
Guatemala	1,008	—	—	—	—	1,008	—	—	—
Honduras	1,200	504	2,016	504	—	—	1,008	—	—
Jamaica	12,024	1,000	6,000	—	—	19,320	—	—	—
Nicaragua	5,016	—	—	5,328	—	5,004	—	—	7,992
Panama	96	108	—	180	—	504	—	—	1,800
Paraguay	32,976	—	2,016	1,008	—	1,512	2,016	—	1,800
Surinam	1,008	—	—	—	—	1,008	—	—	—
Venezuela	9,960	—	—	—	—	9,972	—	—	—
Other[b]	8,094	72	1,512	252	—	7,524	108	1,656	—
Subtotal	125,650	46,876	13,560	16,308	8,000	68,892	16,020	2,160	56,484
TOTAL	**276,646**	**109,168**	**173,544**	**35,892**	**163,096**	**119,608**	**45,540**	**27,714**	**68,401**

[a] For earlier years, see **Population Reports,** Series H, Number 3, *Vaginal Contraceptives—A Time for Reappraisal?*, January 1975, pp. H-49-50.
[b] Other Latin America—Antigua, Aruba, Barbados, Curaçao, Dominica, Guadeloupe, Grenada, Martinique, St. Kitts, St. Lucia, St. Vincent, and Trinidad and Tobago

Source: Office of Population, US Agency for International Development (196)

Table 3. Deliveries of Spermicidal Contraceptives Financed by Family Planning International Assistance, by Year, 1972-1978

Year	Foam (average 100 gram containers)	Jelly (average 135 gram tubes)
1972	15,154	—
1973	25,105	3,569
1974	42,456	1,188
1975	53,148	720
1976	40,162	5,030
1977	41,606	5,472
1978	99,124	7,366
TOTAL	**316,755**	**23,345**

Source: R. Pomeroy, Family Planning International Assistance (140)

Table 4. Deliveries of Spermicidal Contraceptives Financed by the International Planned Parenthood Federation, by Recipient Country, 1975-1978

	Pressurized Foam (in 90 g containers)				Foaming Tablets[a] (in 20-tablet containers)			Jelly/Cream (in 135 g tubes)			
Country	1975	1976	1977	1978	1975	1976	1977	1975	1976	1977	1978
AFRICA											
Benin	1,008	—	1,008	1,008	500	—	2,000	1,008	—	504	1,224
Botswana	96	—	240	324	1,000	—	—	—	—	252	504
Egypt	—	—	108	—	3,000	4,000	10,000	612	—	1,008	1,008
Ethiopia	—	—	672	504	—	—	—	—	—	108	—
The Gambia	504	1,008	240	—	—	—	—	—	—	—	—
Ghana	1,200	—	8,016	4,512	50,000	90,000	210,000	1,704	1,008	3,996	10,008
Kenya	—	—	504	—	—	—	3,000	360	—	—	—
Lesotho	144	1,008	—	1,008	700	1,000	3,000	—	1,008	—	—
Liberia	—	1,008	—	—	500	2,000	2,000	—	—	—	—
Mauritius	216	—	—	—	10,000	—	—	216	—	—	—
Morocco	—	—	—	—	—	—	—	—	—	—	1,008
Nigeria	1,440	1,500	—	—	10,000	10,000	—	1,008	1,008	—	—
Seychelles	216	300	—	—	—	1,000	—	216	360	—	504
Sierra Leone	—	—	—	—	10,000	—	—	2,016	—	—	5,000
Sudan	—	—	—	—	—	—	1,000	—	—	—	—
Tanzania	2,016	1,200	2,520	6,012	2,000	1,000	3,000	1,224	576	2,016	2,016
Togo	—	—	—	504	—	—	—	—	—	—	468
Tunisia	—	—	—	—	—	—	1,000	—	—	—	—
Uganda	—	—	3,000	1,224	—	1,000	5,000	—	—	—	720
Zambia	—	—	—	—	5,000	—	2,000	504	—	—	—
Other[b]	—	600	—	972	9,500	10,000	3,000	504	—	—	—
Subtotal	6,840	6,624	15,300	16,068	108,500	120,000	272,000	9,372	3,960	7,884	22,460
ASIA & PACIFIC											
Afghanistan	—	—	—	—	500	—	—	—	—	—	—
Bangladesh	7,200	3,024	6,024	5,004	15,000	—	—	2,412	—	1,008	5,004
Cyprus	—	36	—	—	1,000	—	—	—	1,440	—	—
Hong Kong	—	—	—	—	2,000	—	7,000	—	—	—	—
Iran	504	42	—	—	—	—	1,000	5,004	5,040	2,016	—
Iraq	1,008	—	3,000	—	4,000	4,000	10,000	—	2,016	—	—
Jordan (Jerusalem)	—	42	—	1,008	—	—	—	—	—	—	—
Laos	—	—	—	—	—	—	—	1,008	—	—	—
Lebanon	96	42	—	612	500	4,000	2,000	216	504	504	—
Malaysia (Sabah)	144	552	120	—	3,000	3,500	—	756	252	—	—
Nepal	5,016	—	—	2,016	5,000	—	—	5,004	—	—	1,512
Pakistan	5,520	10,008	—	8,016	10,000	—	10,000	5,008	—	—	—
Philippines	—	—	—	—	—	200,000	200,000	—	—	—	—
Solomon Islands	—	—	—	—	—	—	1,000	—	—	—	—
Sri Lanka	—	—	—	252	—	—	—	720	504	504	—
Syria	—	—	—	—	—	—	—	—	5,040	—	—
Thailand	—	—	—	—	—	—	20,000	144	—	—	—
Yemen	—	—	—	—	—	—	3,000	—	—	—	—
Subtotal	19,488	13,746	9,144	16,908	41,000	211,500	254,000	19,056	14,796	3,528	6,516

(Continued on next page)

Table 4 (Continued)

Country	Pressurized Foam (in 90 g containers)				Foaming Tablets[a] (in 20-tablet containers)			Jelly/Cream (in 135 g tubes)			
	1975	1976	1977	1978	1975	1976	1977	1975	1976	1977	1978
LATIN AMERICA											
Argentina	—	—	—	—	—	—	—	—	—	—	2,016
Barbados	1,008	—	—	—	2,500	1,000	2,000	—	—	—	—
Bolivia	1,008	1,692	—	—	1,000	1,000	3,000	—	864	—	—
Chile	5,016	—	—	9,036	—	1,000	1,000	5,004	—	—	5,004
Colombia	19,200	20,016	—	—	100,000	70,000	139,000	—	—	—	—
Costa Rica	5,016	5,256	—	—	—	—	—	10,008	10,008	—	12,024
Dominican Rep.	6,000	8,028	—	—	30,000	40,000	20,000	—	108	—	—
Ecuador	2,016	1,008	2,016	2,016	2,000	2,000	3,000	2,016	—	2,304	3,024
El Salvador	—	—	—	—	2,000	—	—	6,012	—	—	—
Grenada	1,008	—	—	—	1,500	2,500	3,000	1,008	—	—	—
Guatemala	1,008	—	—	—	10,000	—	—	1,008	—	—	10,008
Honduras	1,200	504	2,004	504	500	1,000	2,000	—	1,008	—	—
Jamaica	—	—	—	—	—	—	1,000	—	—	—	—
Nicaragua	5,016	—	—	5,328	5,000	5,000	22,000	5,004	—	—	7,992
Panama	96	108	—	180	1,000	—	1,000	504	—	—	1,800
Paraguay	1,008	—	2,016	1,008	1,500	—	5,000	1,512	2,016	1,800	—
St. Kitts	96	—	144	216	—	1,000	2,000	—	—	144	—
St. Lucia	—	—	252	252	5,000	3,000	3,000	—	—	1,008	—
St. Vincent	612	—	—	—	500	—	1,000	612	—	—	—
Surinam	1,008	—	—	—	3,000	—	—	1,008	—	—	—
Trinidad	5,328	—	—	—	20,000	—	—	4,896	—	—	—
Uruguay	—	—	—	—	—	—	1,000	—	—	—	—
Venezuela	9,960	—	—	—	10,000	—	—	9,976	—	—	—
Other[c]	1,008	72	1,080	—	—	—	—	1,008	—	640	—
Subtotal	66,612	36,684	5,496	18,540	195,000	127,500	209,000	49,576	14,004	6,012	41,868
TOTAL	**92,940**	**47,054**	**30,940**	**51,516**	**345,000**	**459,000**	**735,000**	**78,004**	**32,760**	**17,424**	**70,844**

[a] 1978 data not available
[b] Other Africa—Nairobi Regional Office, Lome Sub Regional Office
[c] Other Latin America—Antigua, Curaçao, Montserrat, Falkland Islands

Source: Chapman, Sosler, International Planned Parenthood Federation (36, 177)

Table 5. Direct Purchases of Neo Sampoon Loop Tablets Financed by the United Nations Fund for Population Activities, by Recipient Country, 1974-1978 (in 20-tablet containers)

Country	Purchasing Organization	1974	1975[a]	1976	1977[b]	1978
Algeria	UNICEF	—	3,884	1,000	—	8,000
El Salvador	UNICEF	—	(6,075)	—	—	—
Jordan	UNICEF	—	—	—	350	350
Mauritius	UNICEF	7,000	8,400 (9,000)	13,000	9,000	15,000
Paraguay	UNICEF	—	—	1,500	—	—
Singapore	UNICEF	9,000	12,992	5,976	—	—
Sudan	WHO	—	—	—	—	1,500
Swaziland	UNICEF	—	—	—	1,500	1,000
Togo	WHO	—	—	—	—	1,800
Tonga	UNICEF	—	(200)	—	—	—
Tunisia	UNICEF	—	(200)	—	—	—
Yemen	WHO	—	—	—	—	5,000
TOTAL		**16,000**	**32,476**	**29,576**	[b]	**32,650**

UNICEF = United Nations Childrens Fund
WHO = World Health Organization
[a] Figures in parentheses indicate additional shipments from a stockpile.
[b] Figures may be incomplete due to outstanding purchase orders.

Source: D. Badham, United Nations Fund for Population Activities (12)

Table 6. Spermicidal Contraceptives Provided by the International Planned Parenthood Federation and Distributed to Acceptors, by Country, 1975-1977

Country	Pressurized Foam (in 90 g containers)			Foaming Tablets (in 20-tablet containers)			Jelly (in 135 g tubes)		
	1975	1976	1977	1975	1976	1977	1975	1976	1977
AFRICA									
Benin	237	579	192	350	700	2,000	354	609	—
Botswana	99	82[a]	63	200	927[a]	—	300	212[a]	102
Ethiopia	249	484	313[b]	35	731	242[b]	47	86	64
The Gambia	744	72	—	—	750	400	—	—	—
Ghana	3,501	5,869	5,369	48,508	83,317	157,842	3,808	2,402	5,145
Kenya	369	196	174	1,680	2,989	1,532	188	307	207
Lesotho	714	123	1,181	180	838	2,709	4	110	367
Liberia	206	—	349	282	—	934	30	—	83
Mali	—	2	52	—	—	12	—	—	12
Mauritius	61	60	—	1,333	1,526	—	34	12	—
Nigeria	192	219	582	1,503	2,293	4,884	16	134	250
Seychelles	120	—	—	—	—	—	93	—	—
Sierra Leone	510	464	714	2,403	4,230	—	88	306	503
Tanzania	528	1,990[c]	120	1,510	510[c]	2,030	840	580[c]	680
Uganda	683	29	—	—	760	1,492	—	26	61
Zambia	200	98	193	1,083	2,131	1,764	198	211	65
Subtotal	8,413	10,267	9,302	59,067	101,702	175,841	6,000	4,995	7,539
ASIA & PACIFIC									
Afghanistan	7,015	5,040	9,468	—	180	320	6,336	20,004	17,660
Bangladesh	4,210	4,359	7,766	2,280	2,606	3,985	1,699	2,545	1,211
Cyprus	—	—	35	60	—	—	109	88	121
Egypt	—	—	—	841	—	—	4,735	—	—
Hong Kong	482	459	553	3,133	4,177	3,831	2,422	3,875	4,833
India	—	—	—	1,072	2,741	1,798	785	725	748
Indonesia[d]	—	—	—	16,100	—	—	—	—	—
Iran	7	55	153	1,000	200	1,200	1,080	2,198	1,736
Iraq	445	—	—	4,000	—	1,000	—	—	—
Jordan (Jerusalem)	62	22	—	—	—	—	—	9	51
Lebanon	250	—	73	—	200	70	300	60	60
Malaysia	97	89	210	716	1,900	1,828	2,723	598	—
Morocco	—	—	—	—	—	—	1	840	152
Nepal	2,143	1,926	2,082	1,531	2,220	1,524	1,527	2,032	1,844
Pakistan	2,864	5,308	4,701	4,585	4,701	3,014	2,866	3,130	2,744
Philippines	NA	1,625	1,839	NA	1,285	2,447	NA	195	438
Malaysia (Sabah)	—	28	46	417	730	522	151	153	103
Malaysia (Sarawak)	2	105	131	202	732	942	2	41	56
Solomon Islands	—	50	20	—	—	50	—	—	1
Sri Lanka	—	—	—	—	—	—	258	336	488
Sudan	16	100	—	100	300	1,000	90	—	—
Syria	—	—	—	—	—	328	—	—	292
Thailand	1,014	8	1	13,062	2,090	1,577	1,511	8	1
Yemen	—	—	—	—	—	983	—	—	—
Subtotal	18,607	19,174	28,078	49,099	24,062	26,419	26,595	36,837	32,539
LATIN AMERICA & CARIBBEAN									
Antigua	590	184	52	—	—	—	432	—	30
Aruba	5	—	—	—	—	—	9	7	7
Barbados	241	416	1,591	371	1,561	480	691	1,024	1,011
Bolivia	20	250	278	691	1,069	—	—	—	—
Chile	5,696	2,793	51	—	545	465	5,143	5,314	1,260
Colombia	4,189	9,321	12,018	15,570	55,303	79,287	4,722	5	24
Costa Rica	2,249	10,876	4,030	18	55	—	3,951	—	—
Curaçao	44	91	199	—	—	—	78	66	103
Dominican Republic	454	35	1,905	2,303	938	3,823	24	8	64
Ecuador	701	543	2,758	1,636	3,140	2,069	1,476	1,168	1,633
El Salvador	—	772	1,067	836	2,086	1,018	—	506	995
Grenada	126	1,145	1,147	1,550	1,840	567	458	1,129	270
Guatemala	709	309	1,113	1,019	2,223	8,173	689	574	4,237
Honduras	563	828	537	923	800	—	68	—	128
Jamaica	550	395	512	765	4	863	772	701	715
Mexico	—	—	—	—	—	2,951	—	—	—
Montserrat	59	34	15	—	92	217	29	10	17

(Continued on next page)

Table 6 (Continued)

Area and Country	Pressurized Foam (in 90 g containers)			Foaming Tablets (in 20-tablet containers)			Jelly (in 135 g tubes)		
	1975	1976	1977	1975	1976	1977	1975	1976	1977
Nicaragua	964	3,370	649	2,814	5,355	1,254	180	2,248	1,500
Panama	55	18	36	173	68	252	36	26	78
Paraguay	1,224	596	—	1,980	2,228	—	1,338	598	—
St. Kitts/Nevis	66	108	48	442	158	270	25	—	5
St. Lucia	2,592	1,044	—	2,300	794	—	916	—	—
St. Vincent	225	60	51	59	—	137	65	58	62
Surinam	—	—	—	—	—	37	—	—	52
Trindad & Tobago	1,974	1,368	589	6,290	12,300	10,084	1,353	1,419	870
Uruguay	—	—	—	—	—	972	—	—	—
Subtotal	23,296	34,556	28,057	39,740	90,559	112,919	22,455	14,861	13,061
TOTAL	**50,316**	**63,997**	**65,437**	**147,906**	**216,323**	**315,179**	**55,050**	**56,693**	**53,139**

NA = not available
[a] Botswana 1976—Reported as issued to clinics
[b] Ethiopia 1977—Includes some transfer of stock to clinics
[c] Tanzania 1976—Issues to UMATI (Tanzanian Family Planning Association) clinics
[d] Indonesia—Includes some stock movement

Source: IPPF (91, 92, 93)

MANUFACTURERS OF SPERMICIDAL CONTRACEPTIVES

Name & Address	Product(s)
Dr. Herbrand KG. Chem.-Pharm. Werk D-7614 Gengenbach/Baden Fed. Rep. of Germany	A-gen 53/Syn-a-gen (s)
Eaton-Merz Laboratories, Inc. 13-27 Eaton Avenue Norwich, New York 13815 USA	Encare (s)
Eisai Company, Ltd. International Division 5-5, Koishikawa 5-chome Bunkyo-ku, Tokyo 112 Japan	Neo Sampoon (t)
Holland-Rantos Company, Inc. P.O. Box 385, 865 Centennial Avenue Piscataway, New Jersey 08854 USA attn: Medical Service Department	Koromex II Cream Koromex II Jelly Koromex II-A Jelly Koromex Foam
Jordan-Simner, Inc. 6852 N.W. 12th Avenue Fort Lauderdale, Florida 33309 USA	S'positive (s)
Koronis GmbH D5441 Sassen Fed. Rep. of Germany	Lady Suppositories Contraceptivum E (s)
Laboratoires Human-Pharm S.A. 94 rue Ed.-Vaillant 92532 Levallois-Perret France	Ta-ro-cap ("soluble [cervical] cap")
Laboratoires Labaz 39 Avenue Pierre 1er de Serbie 75008 Paris France	Gelifax (j)
Luitpold-Werk Chem.-Pharm. Fabrik Postfach 701209 8000 Munchen 70 Fed. Rep. of Germany	Semori (t)
Lusofarmaco Istituto Luso Farmaco d'Italia 20132 Milano Via Carnia 26 Italy	Agena (c) Agena (s)
Norwich International Division of Morton-Norwich Products, Inc. 410 Park Avenue New York, New York 10022 USA	
Laboratorios Eaton Vemaco Ltda. Caixa Postal 7194 ECP 01000 São Paulo Brazil	Lorophyn (s) Norforms (s)
Norwich Colombiana S.A. D.E. Transversal 42B 19-77 Apartado Aereo 13902 Bogotá Colombia	Lorophyn (s) Norforms (s)
Norwich Eaton Argentina Recuerdos de Provincia 4572 Casilla de Correo 2-Suc. 54-B Buenos Aires Argentina	Lorophyn (s) Norforms (s)
Norwich Pharmacal Company del Peru, S.A. Avenida Alfonso Ugarte No. 873 Office 803-804 Lima Peru	Lorophyn (s) Norforms (s)
Norwich Pharmacal Company de Mexico Avenida Coyoacan Num 1895 Mexico, 12 D.F.	Profam (s) Lorophyn (s) Norforms (s)
Simoniz Do Brasil Avenida Itaoca 1939 Galpao D Rio de Janeiro Brazil	Lorophyn (s) Norforms (s)
Nova Corporation of America P.O. Box 382 Cos Cob, Connecticut 06807 USA	Flavo-cept (raspberry) (c)
Ortho Pharmaceutical Corporation Raritan, New Jersey 08869 USA	Orthogynol (j) Conceptrol (c) Delfen (c) Ortho-Creme (c)

Name & Address	Product(s)
Patentex GmbH Marschnerstrasse 8-10 6 Frankfurt (Main) 1 Fed. Rep. of Germany	Patenex (f) Patentex (j) Patentex Oval (s) Antibion (t)
Petri GmbH and Company KG. Chem.-Pharm. Präparate Postfach 510320 7500 Karlsruhe 51 Fed. Rep. of Germany	Si-O-Safety (s)
Pharmasal H. Franzke KG. 3005 Hemmingen Carl-Zeiss-strasse 40 Fed. Rep. of Germany	Confidol (j)
Potter and Clarke Ltd. 415 Limpsfield Road The Green Warlingham Surrey CR3 9YS UK	C-Film
Schering Corporation Galloping Hill Road Kenilworth, New Jersey 07033 USA	Because (f) Emko (f) Emko Pre-fil (f)
Schmid Laboratories, Inc. Route 46 West Little Falls, New Jersey 07424 USA	Ramses (j)
Syntex Pharmaceuticals Limited St. Ives House St. Ives Road Maidenhead, Berkshire SL6 1RD UK	Staycept (j) Staycept (s)
Temmler-Werke Postfach 2269 D-3550 Marburg Fed. Rep. of Germany	Speton (t)
Whitehall Laboratories Inc. 685 3rd Avenue New York, New York 10017 USA	Semicid (s)
W. J. Rendell, Ltd. Ickleford Manor Hitchin Herts SG5 3XE England	Rendells (s) Genexol (s)
Yamanouchi Pharmaceutical Co., Ltd. No. 5, 2 Chome Nihonbashi, Honcho Chuo-Ku Tokyo Japan	CCC (t) CCC (j)

c = cream f = pressurized foam j = jelly s = suppository t = tablet

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Figure 8. In Bangladesh, Concerned Women for Family Planning, with the assistance of the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), is developing and testing instructions for illiterate women in the use of "Joy" foaming spermicidal tablets. These pictures from a draft brochure illustrate some of the problems involved: for example, while no health care organization wants to appear to promote smoking, it has proved difficult to find any other way to make clear to people who may not be familiar with clocks the need to wait approximately 5 minutes after insertion and before intercourse so that the tablet can dissolve completely. (M. Zimmerman, Piact)

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